Approved
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Trinity Health Of New England | Saint Mary's Hospital

Office of the President
Steven E. Schneider, M.D., M.B.A.

January 28, 2019

Susan Newton, R.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section
410 Capitol Avenue
MSH #12HSR
PO Box 340308
Hartford, CT 06134

Dear Ms. Newton:

Enclosed is the Plan of Correction we have developed for violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of unannounced visits at Saint Mary's Hospital concluding on December 6, 2018 by a representative of the Facility Licensing and Investigation Section of the Department of Public Health.

The Plan of Correction reflects the measures to prevent a recurrence of the identified violations, the effective date in which compliance will be achieved and the identity of the staff members by role who are responsible for monitoring the Plan of Correction as required.

If you have additional questions, please feel free to contact Lisa Fucci at 203-709-3682.

Respectfully,

Steven Schneider, M.D., M.B.A.
President

			STATEMENT OF VIOLATIONS	Date of Inspection:
Saint Mary's Hospital	56 Franklin Street, Waterbury, Connecticut 06706			
Public Health Code Section #	Summary Statement of Violations		Corrective Actions/Responsibilities	Completion Date May 3, 2018
Section 19-13-D3 (b) Administration (2).	1. Based on a review of hospital documentation, a review of policies and procedures, a review of committee meeting minutes and interviews, the hospital failed to comprehensively collect and analyze data for the department of anesthesia, laboratory services and multiple other departments to monitor the effectiveness and safety of services and quality of care. The finding included: a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee. Review of the reporting schedule for year 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have a record of the reporting schedule for 2016 or 2017. Interview with the Director of Quality on 9/28/18 at 11:00am indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Further interview identified that she was not aware that each department would be responsible to identify high risk areas, collect data, analyze the data, take action aimed at performance improvement, track performance to ensure sustainability, and to report the information to the quality committee on a routine basis. Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and that each department had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect		Applies to 19-13-D3 (b) Administration (2). Quality of Care Committee created to provide leadership and ownership to the hospital's efforts to improve health outcomes and to prevent and reduce medical errors. The Committee's core structure consists of the Chief Medical Officer, Chief Nursing Officer, the Medical Director of Quality, the Manager of Quality, Director of Regulatory and Medical Staff Affairs, Risk Management, and Director of Nursing Practice. The Committee's charter was endorsed and approved by the Hospital Executive Leadership and the Quality & Patient Safety Committee of the Board. Leaders from all clinical and non-clinical areas will be present to attend at the time of their designated reporting schedule. The department reporting structure was created to include all departments including contracted services. A template (A3) was developed to guide departments in their reporting responsibilities that includes metrics specific to the department, including challenges, barriers, high risk and problem prone area. The A3 template will keep track of the department specific project activity and regulatory readiness. The Quality of Care Committee has the oversight to ensure metrics are consistent to target, that a suitable action plans is in place and is maintained. Monitoring: The Quality of Care Committee will report directly to the Quality and Patient Safety Committee of the Board through minutes as well as direct report of the Committee's activities. Responsibility: Chief Medical Officer	Completion Date. November 5, 2018 October 25, 2018 October 25, 2018 November 1, 2018 November 29, 2018

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	the betterment of health care outcomes in all areas. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclnsive and comprehensive was likely due to the transition in leadership of the hospital. Review of the Performance Improvement Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would also be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activities provided by personnel delivering direct care and support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies.			
Section 19-13-D3 (b) Administration (2).	2. Based on review of hospital documentation, a review of policies and procedures, a review of committee meeting minutes and staff interviews, the hospital failed to comprehensively focus on high risk, or problem prone areas and take action at performance improvement activities, measure its success and ensure sustainability for the department of anesthesia, pharmacy, laboratory services and multiple other departments.		Applies to Section 19-13-D3 (b) Administration (2) Quality of Care Committee created to provide leadership and ownership to the hospital's efforts to improve health outcomes and to prevent and reduce medical errors. The Committee's core structure consists of the Chief Medical Officer, Chief Nursing Officer, the Medical Director of Quality, the Manager of Quality, Director of Regulatory and Medical Staff	November 5, 2018

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	The finding included: a. Interview and review of tbe quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 am failed to identify that the department of anesthesia, laboratory services and multiple other departments reported to the quality committee. Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have record of the reporting schedule for 2016 or 2017. Further interview with the Director of Quality on 9/28/18 at 11:00am indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that each department would be responsible to identify high risk areas, collect, analyze data, take action aimed at performance improvement, track performance to ensure sustainability and to report the information to quality on a routine basis. Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and that each department had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership of the hospital. Review of the Performance Improvement	Affairs, Risk Management, and Director of Nursing Practice. The Committee's charter was endorsed and approved by the Hospital Executive Leadership and the Quality & Patient Safety Committee of the Board. Leaders from all clinical and non-clinical areas will be present to attend at the time of their designated reporting schedule. The department reporting structure was created to include all departments including contracted services with a focus on each departments high risk areas. A template (A3) was developed to guide departments in their reporting responsibilities that includes metrics specific to the department, including challenges barriers, high risk and problem prone areas. The A3 template will keep track of the department specific project activity and regulatory readiness. The Quality of Care Committee has the oversight to ensure metrics are consistent to target, that a suitable action plans is in place and is maintained. Monitoring: The Quality of Care Committee will report directly to the Quality and Patient Safety Committee of the Board through minutes as well as direct report of the Committee's activities. Responsibility: Chief Medical Officer	October 25, 2018 October 25, 2018 November 1, 2018 November 29, 2018

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	Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activittes provided by personnel delivering direct care and support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies.			
Section 19-13-D3 (b) Administration (2).	3. Based on review of hospital documentation, review of policies and procedures, review of committee meeting minutes and interviews, the hospital failed to develop annual improvement projects for the departments of anesthesia, pharmacy, laboratory including multiple other departments. The finding included: a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 AM failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee. Further review of the quality committee minute meeting dated October 2016 to August of 2018 failed to identify annual improvement projects. Review of the reporting schedule dated 2018 for the		Applies to 19-13-D3 Administration (2). Quality of Care Committee created to provide leadership and ownership to the hospital's efforts to improve health outcomes and to prevent and reduce medical errors. The Committee's core structure consists of the Chief Medical Officer, Chief Nursing Officer, the Medical Director of Quality, the Manager of Quality, Director of Regulatory and Medical Staff Affairs, Risk Management, and Director of Nursing Practice. The Committee's charter was endorsed and approved by the Hospital Executive Leadership and the Quality & Patient Safety Committee of the Board. The annual priority strategic goals selected by the Quality and Patient Safety Committee of the Board had been incorporated into the hospital wide performance	November 5, 2018 October 25, 2018

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	Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have record of the reporting schedule for 2016 or 2017. Review of the Performance Improvement Management Plan dated January 2016 failed to identify that annual improvement projects were the responsibility of the quality committee. Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that annual improvement projects should have been identified and incorporated into the Performance Improvement Management Plan. Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Additionally, the CNO and CMO were not aware that the annual improvements had not been identified for 2018. Further interview with the CNO and CMO indicated they were hired in February of 2018 and identified the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership.	improvement program. The 2018 priority strategic goals included the reduction of hospital acquired infections, reduction in readmission for any reason, and improvement in care coordination post discharge. The Performance Improvement Management policy was modified to include clarification that the Quality of Care Committee is responsible for the oversight of identifying and tracking annually the performance improvement initiatives throughout the hospital. This statement is also captured in the Board approved charter. Monitoring: The Quality of Care Committee will report directly to the Quality and Patient Safety Committee of the Board through minutes as well as direct report of the Committee's activities. Responsibility: Chief Medical Officer	July 1, 2018 October 31, 2018 November 29, 2018

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Section 19-13-D3 (b) Administration (2).	4. Based on review of hospital policies, a review of facility documentation, review of hospital meeting minutes and interviews, the hospital failed to ensure anesthesia, pharmacy, laboratory, and multiple other departments were incorporated in the hospital-wide QAPI (Quality Assurance Performance Improvement) Committee. The finding included: a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee. Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. Further review identified that the hospital failed to have record of the reporting schedule for 2016 or 2017. Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that each department would be responsible to identify high risk areas, collect, analyze data, take action aimed at performance improvement, track performance to ensure sustainability and to report the information to	Applies to 19-13-D3 (b) Administration (2). Quality of Care Committee created to provide leadership and ownership to the hospital's efforts to improve health outcomes and to prevent and reduce medical errors. The Committee's core structure consists of the Chief Medical Officer, Chief Nursing Officer, the Medical Director of Quality, the Manager of Quality, Director of Regulatory and Medical Staff Affairs, Risk Management, and Director of Nursing Practice. The Committee's charter was endorsed and approved by the Hospital Executive Leadership and the Quality & Patient Safety Committee of the Board. Leaders from all clinical and non-clinical areas will be present to attend at the time of their designated reporting schedule. The department reporting structure was created to include all departments including contracted services. A template (A3) was developed to guide departments in their reporting responsibilities that includes metrics specific to the department, including challenges barriers, high risk and problem prone areas. The A3 template will keep track of the department specific project activity and regulatory readiness. The Quality of Care Committee has the oversight to ensure metrics are consistent to target, that a suitable action plans is in place and is maintained. Monitoring: The Quality of Care Committee will report directly to the Quality and Patient Safety Committee of the Board through minutes as well as direct report of the Committee's activities.	November 5, 2018

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	quality on a routine basis. Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 pm indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership. Review of the Performance Improvement Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activities provided by personnel delivering direct care/support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies. Further review of the Performance Improvement Management Plan dated January 2016 directed that	Responsibility: Chief Medical Officer	

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	the Quality and Patient Safety Committee would assist the board in overseeing and ensuring the quality of clinical care and patient safety for the hospital. The Board of Directors would maintain ultimate responsibility for the effectiveness of the performance improvement management system.			

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Section 19-13-D3(b) Administration (2).	5. Based on review of hospital documentation, review of policies and procedures, review of committee meeting minutes and staff interviews, the hospital failed to comprehensively address priorities for improved quality care and determine the number of distinct improvement projects to be conducted annually. The finding included: a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee. Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals.The hospital failed to have record of the reporting schedule for 2016 or 2017. Further review of the quality committee minute meeting dated October 2016 to August of 2018 failed to identify annual improvement projects. Review of the Performance Improvement Management Plan dated January 2016 failed to identify that annual improvement projects were part of the responsibility of the quality committee. Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that annual improvement projects should have been identified and incorporated into the Performance Improvement Management Plan. Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Additionally, the		Applies to 19-13-D3 ( ) Administration (2). A data/project tracking template (A3) was created to capture the types of projects conducted by each department and specifies goals, targets of compliance and measures of success. The Hospitals Organizational chart was utilized to capture all departments within the hospital, as well as contracted service programs that will be required to report to the Quality of Care Committee. All hospital departments and contracted services will report biannually or when the Committee determines a concern regarding performance improvement activities and/or when an adverse event occurs. The Performance Improvement Management policy was modified to include clarification that the Quality of Care Committee is responsible for the oversight of identifying and tracking annually the performance improvement initiatives throughout the hospital. This statement is also captured in the Board Quality of Care Committee approved charter. Monitoring: The Quality of Care Committee will report directly to the Quality and Patient Safety Committee of the Board through minutes as well as direct report of the Committee's activities. Responsibility: Chief Medical Officer	November 1, 2018 October 25, 2018 October 31, 2018 November 29, 2018

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	CNO and CMO were not aware that the annual improvements had not been identified for 2018. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership.			

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Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6).	6. *Based on observation, a review of facility documentation, interviews, and policy review, the hospital failed to provide the necessary supervision of pharmacy services to ensure that policies and procedures were developed and comprehensive related to the preparation of compounding medications, and/or failed to provide evidence of staff training, and/or failed to ensure a process was in place to monitor adherence to the policies and procedures in accordance with Federal and/or state laws, United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding (USP-797). The findings include: a. During a tour of the pharmacy on 10/3/18 with the Department of Consumer Protection (DCP), it was noted that multiple compounded medications located in the refrigerator were absent a label that identified beyond use dating (BUD) and/or a multidose vial of Gentamycin was not labeled with the BUD. Interview with the Director of the Pharmacy on 10/3/18 indicated that the pharmacy staff had been utilizing expiration dates for most sterile compounding preparations that identified a two day expiration date. Subsequent to the surveyor inquiry with the Director of Pharmacy identified that all Compounded Sterile Preparations (CSP's) would be immediately labeled with the appropriate BUD in accordance with USP 797 guidelines. b. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to wash hands for thirty second up to their elbow. c. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to clean their fingernails with a nail pick. d. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to dry their hands with	Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). On going supervisory oversight of the Pharmacy services will be performed by the Vice President of Operations. In addition, Pharmacy will be required to report activities related to USP797/800 to the Quality and Patient Safety Committee of the Board. Monitoring: The Director of Pharmacy will report to the Vice President of Operations all pharmacy USP797/800 activities related to policy changes and updates, competency training, environmental testing and conditions; and infection prevention issues related to compounding twice monthly for 6 months. In addition, Pharmacy will report USP797/800 activities the Quality and Patient Safety Committee of the Board. Responsibility: Vice President and Chief Operating Officer Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). a) Beyond Use Dating (BUD) immediately corrected while surveyors on site. Staff re-educated that the BUD is the date that identifies the date by which the compounded sterile preparations (CSP) must begin administration before it is at risk for chemical degradation or contamination. Monitoring: Appropriate Beyond Use Date labeling will be audited for 3 times per week for 4 weeks. Responsibility: Manager of Pharmacy	November 7, 2018 May 31, 2019 Indefinite October 3, 2018 October 15, 2018 November 30, 2018

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	a non-shedding towel. e. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmacy Technician was wearing makeup. f. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmacist had exposed skin. g. During a tour of the pharmacy on 10/3/18 it was observed that Environmental staff failed to wear a gown that provided appropriate coverage. h. During a tour of the pbarmacy on 10/3/18 it was observed that tbe Pbarmacy Technician failed to dispose of gowns and could not identify if the gown was reusable per manufacturers recommendation. i. During a tour of the pharmacy on 10/3/18 it was observed that Pbarmaceutical staff failed to utilize sterile gloves during compounding preparation and failed to don sterile gloves over the isolator gloves. j. During a tour of the pbarmacy on 10/3/18 it was observed that the Environmental and Pharmacy Techician failed to use a waterless based alcohol scrub subsequent to leaving the isolator and prior to resuming compounding. k. During a tour of the pbarmacy on 10/3/18 it was observed that Environmental services and the Pharmacy Technician placed a shoe covers on their feet and failed to step across the line of demarcation in accordance with USP 797. l. During a tour of the pbarmacy on 10/3/18 it was observed that reusuable mop bandles were not in original working condition and not labeled. m. During a tour of the pharmacy on 10/3/18 it was observed that the Pbarmaceutical staff and Environmental Services failed to differentiate mini-mop handles used for the bazardous versus tbe non-hazardous isolator. n. During a tour of the pharmacy on 10/3/18 it was observed the Environmental staff failed to document the mixing and diluting of cleaning and sanitizing agents via a log.	Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6), b) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for handwashing and fingernail cleaning. All pbarmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pbarmacy (1)(2)(3)(4) and/or (i) General (6), c) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey whicb is specifically for IV compounding and describes instructions for handwashing, fingernail cleaning. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring:	October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018

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	o. During a tour of the pharmacy on 10/3/18 it was observed that all Pharmaceutical Techniciaan's failed to appropriately label the sterile isopropyl alcohol when it was opened or the expiration date. p. During a tour of the pharmacy on 10/3/18 it was observed that the Environmental staff failed to document that the cart utilized in the segregated compounding area was cleaned daily. q. During a tour of the pharmacy on 10/3/18 it was observed that a fatigue mat was utilized however the documentation failed to identify how it was cleaned and/or appropriate for use. r. During a tour of the pharmacy on 10/3/18 it was observed that a tacky mat was utilized outside of the segregated compounding area and failed to be located directly in front of the entry door. s. During a tour of the pharmacy and a review of the manufacturers guidelines for cleaning of the isolators on 10/3/18 it was identified that the dwell time should be ten minutes however, an observation indicated the drying time in parts of the isolator was ninety seconds, and the technician failed to rewet the surfaces to ensure the appropriate dwell time. t. During a tour of the pharmacy on 10/3/18 it was observed the facility failed to have non-permeable surfaces to ensure appropriate cleaning ie. wood doors, particle boards under counters, walls and ceilings. u. During a tour of the pharmacy on 10/3/18 it was observed in the sterile compounding room that the facility failed to ensure walls were painted with epoxy based paint and bare wood was observed. v. During a tour of the pharmacy on 10/3/18 it was observe in the sterile compounding room that the facility failed to ensure that light fixtures were sealed. w. During a tour of the pharmacy on 10/3/18 it was observed that the segregated compounding area was overstocked with unused sharps containers and a	IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). d) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for handwashing, fingernail cleaning and care, and identifies the use of a non-shedding towel when drying hands. The policy restricts personnel from IV compounding with fever or active respiratory infections, severe sunburn, skin rash or open wounds. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). e) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and instructs staff for handwashing, fingernail cleaning and care, and	November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018

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	large supply of isolator gloves. x. Review of the hospital documentation failed to identify that agar plates were utilized for fingertip testing and that documentation lacked the results, hand designation, the dates, incubation temperature, signature of observer and that daily checking was conducted. y. Review of the hospital documentation failed to identify that media fill tests final results were documented as pass or fail. The documentation failed to include the incubation time or temperature, and/or the media testing procedures did not include the fill volume, inspection of filled units, interpretation of results, and action levels with the correct actions required. z. Review of the hospital documentation failed to identify that compounding and environmental service staff have documented competencies for gowning and handwashing. aa. Review of the hospital documentation failed to identify a risk acknowledgement and/or that compounding personnel had hazardous didactic training and/or that observational assessments were documented. bb. Review of the hospital documentation failed to identify that the compounding containment isolator failed to have documentation that indicated the room in which it is located maintained a minimum of twelve air exchanges per hour. cc. Review of the hospital documentation failed to indicate the volume of the primary engineering control (PEC) when obtaining air samples. dd. Review of the pharmacies standard operating procedures (SOP) identified the hospital failed to comprehensively address SOP's for the clean room regarding cleaning and environmental testing. ee. Review of the pharmacies standard operating procedures identified the hospital failed to address that all sterile compounds would be identified as	prohibits jewelry and makeup. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). f) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and instructs that no skin may be exposed on the legs , feet, or below hem of gown. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist	October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018

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	hazardous. ff. Review of the pharmacies standard operating procedures identified the hospital failed to address if gowns utilized in the sterile compounding room were reusable per manufacturers recommendations and if they were not disposable, where and how would they be stored. gg. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how frequency the tacky mat would be changed or replaced. hh. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed how frequent the tacky matt would be changed or replaced and/or its appropriate location. ii. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP prohibiting personnel from entering the compounding area and/or clean room if they have a sunburn, weepin sores, conjunctivitis or an active respiratory infection. jj. Review of the pharmacies standard operating procedures identified the hospital failed to have an SOP that directed all personnel in the compounding area are required to remove all jewelry and makeup. kk. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that prohibited all personnel from wearing artificial nails or extenders, and that required staff to keep natural nails neat and trimmed. ll. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how frequency the fatigue mat would be changed or replaced. mm. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how every CSP would be visually inspected for the presence of particulate matter,	Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). g) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and instructs that no skin may be exposed on the legs, feet, or below hem of gown. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). h) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and instructs that the gown may be saved for subsequent use during the same compounding shift if not visibly soiled. It also specifies that at no time may any hazardous drug garb be used and must be discarded. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new	October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018

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	evidence of incompatibility or other issues. nn. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed single dose containers, bags, bottles, syringes or vials that were opened or punctured in worse than ISO Class 5 air used within one hour and the remaining contents discarded and/or how are they identified for expiration. oo. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed single dose vials exposed to ISO 5 air or cleaner used within six hours of the initial puncture and any remaining contents discarded and/or how are they identified for expiration. pp. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed multiple dose vials assigned a BUD of 28 days or the manufacturers specific BUD, (whichever was less) after the initial entry or puncture and/or how are multi-dose vials identified for expiration after they have been opened or punctured. qq. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP for in process checks performed by a pharmacist and to ensure that procedures were followed. rr. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed if a CACI (compounding aseptic container isolator) was used, the room in which it was located needed to be certified to a minimum or 12 ACPH (air change per hour). ss. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed all compounding staff would have passed an initial and subsequent annual competency assessments of aseptic compounding skills including handling hazardous drugs and that all pharmacists	policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). i) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for use of sterile gloves. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). i) A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for use of sterile IPA. The policy specifies	November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018

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	and technicians performing compounding using hazardous drugs were appropriately trained in the safe handling, garbing, cleaning, and disinfecting procedures and waste disposal of hazardous drugs and materials. Interview with the Director of the Pharmacy on 10/4/18 at 2:00 PM indicated although the staff was trained in USP 797 guidelines he was unaware of the garbing procedures as this pharmacy had isolators and not a "clean room". Further interview with the Director of Pharmacy identified he did not conduct surveillance of garbing, handwashing or cleaning therefore was unaware that the USP 797 guidelines were not performed in accordance with the regulations. Furthermore, the Director was unaware that the hospital's standard operating procedures were not comprehensive. Interview with the Infection Control Nurse on 10/4/18 at 2:15 PM identified she was new in the role of infection control and although she was aware the compounding room was a high risk area she had not initiated surveillance rounds to ensure garbing, handwashing, cleaning and that all infection control practices were maintained in the aseptic area of the pharmacy. Interview with the Director of Environmental Services on 10/4/18 at 1:20 PM identified he was not aware that a mixing log was needed to verify the appropriate cleaning solutions and their amounts. Additionally, the Director of Environmental Services indicated the Environmental staff was trained on gowning, handwashing and cleaning of the compounding area by the operations manager however documentation of the training was not available. The job description of the pharmacy director in part identified that he/she would oversee the management of the entire scope of the pharmacy department. The director plans, organizes, staffs, directs, controls,	that sterile IPA is used on all surfaces of the isolator gloves at the start of the procedure, after touching any nonsterile items and periodically during prolonged periods of compounding (but no less than 30 minutes). All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. <u>Monitoring:</u> IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. <u>Responsibility:</u> Infection Prevention Specialist <u>Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6), k)</u> A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for use of shoe covers and complying with the marked line for demarcation. All pharmacy and EVS Staff educated to Hand Hygiene and Garbing Policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing for Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy. <u>Monitoring:</u> IV Compounding staff will be audited for hand hygiene	October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018

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	problem-solves, develops staff, reinforces performance and facilitates the work of others. Furthermore, tbe director of the pharmacy updates departmental policies and procedures, ensures departmental compliance with intravenous compounding and regulatory standards. An immediate plan of action dated 10/4/18 directed that a policy would be created for Beyond Use Dating for all CSP's. Expiration dates would no longer be used. All new CSP's would immediately be labeled with a BUD and all other CSP's with expiration dates would be disposed of. In addition, compounding staff would be trained immediately and/or prior to the next working shift by the pharmacy manager. The immediate plan of action directed that a policy would be written for proper hand hygiene for entry into the compounding area including the use of sterile gloves, lint free towels, the use of full gown coverage and garbing in relationship to the line of demarcation. In addition, training would be completed prior to the next working shift by the pharmacy manager and by the infection control nurse. Additionally, the fatigue mat, extra sharp containers, and clutter was removed from the compounding area. Moreover the staff would be immediately trained when cleaning tbe isolators to ensure a dwell time of ten minutes until an alternate cleaning product could be obtained. This training would be conducted by the pharmacy manager prior to the next working shift.	and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). l) Compounding Room Cleaning policy developed during survey which describes care handling and storage of cleaning equipment. The policy identifies that cleaning equipment is for the sole use within the IV compounding room and is labeled. Environmental services Staff educated to policy to the Compounding Room Cleaning policy. Monitoring: The Compounding room cleaning equipment will be audited for handling, storage and labeling will be audited 3 times per week for 4 weeks. Responsibility: General Manager Environmental Services Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). m) Mini mop handles were labeled to specify that the handles were separated and identified for use within the hazardous compounding and non-bazardous compounding hoods. The IV compounding staff were educated to not interchange these mop handles. Monitoring: Will audit 3 times per month for 3 months to ensure that the mob handles are labeled differentiating hazardous from non-hazardous use. Responsibility: Manager of Pharmacy	October 3, 2018 November 2, 2018 November 30, 2018 October 17, 2018 October 17, 2018 January 30, 2019

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		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). n) Immediately began using mixing logs to document the mixing and diluting of cleaning agents. New ready to use product purchased (OxivirTb) which requires no mixing of sanitizing agents within the IV Compounding unit. Mixing logs no longer required. Monitoring: Will audit to ensure that no new chemicals are introduced into IV Compounding area that requires mixing for 3 months. Responsibility: General Manager Environmental Services Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). o) Current policy directed staff to label alcohol with appropriate expiration date. Pharmacy compounding Staff re-trained to policy. Monitoring: Will audit that pharmacy compounding staff are labeling opened bottles of isopropyl alcohol with appropriate expiration date 3 times per week for 4 weeks. Responsibility: Manager of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). p) The standard operating procedure, Pharmacy Compounding Cleaning policy, was developed which describes all surfaces that are required to be cleaned daily. The policy directs that all hard surfaces, shelves and laminar surfaces are cleaned weekly. Environmental services staff re-educated to policy.	October 3, 2018 November 2, 2018 January 30, 2019 November 2, 2018 November 30, 2018 October 18, 2018 November 2, 2018

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		Monitoring: Environmental services staff will be audited 3 times per week for 4 weeks to ensure that all hard surfaces are cleaned per policy. Responsibility: General Manger Environmental Services	November 30, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). q) The fatigue mat was removed at time of survey.	October 3, 2018
		Monitoring: Will audit weekly for one month to ensure that the fatigue mat is not replaced. Responsibility: Manager of Pharmacy	November 30, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). r) Tacky mat immediately repositioned at time of survey. A permanent mark has been placed to assist with appropriate placement of the tacky mat. Monitoring: Responsibility: Director of Facilities	November 2, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). s) New isolator cleaner (PreEmpt) purchased which has a dwell time of 2 minutes. Staff re-educated on use of product to ensure that the dwell time use for the isolator is 2 minutes. Monitoring:	October 25, 2018 November 2, 2018

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		Will audit 3 times per week for 4 weeks to ensure that the dwell time of the cleaning product is adhered to for isolator cleaning. Responsibility: Manger of Pharmacy	November 30, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). **t thru v** Facilities action plan approved through CT Department of Public Health Life Safety Division to replace IV Compounding room wooden door with metal door, approved to 2 part epoxy paint all walls, ceilings and particle board to ensure full encapsulation of all porous material. Light fixtures will be sealed with caulk and polyurethane. Monitoring: Pending on unannounced on site visit from CT Department of Public Health Life Safety Division. Responsibility: Director of Pharmacy Services	October 31, 2018 Pending approval to re-utilize room
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). w Unused sharp containers and extra supply of isolator gloves were immediately removed at time of survey. Monitoring: Will audit 3 times per week for 4 weeks to ensure that extra sharp containers and supply of isolator gloves are not returned to the compounding room. Responsibility: Manger of Pharmacy	October 3, 2018 November 30, 2018

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		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). x and y Compounding Pharmacy Competency policy updated to include agar plates Utilized during glove fingertip testing. Documentation of competency will include results, right or left hand designations, dates, incubation temperature and signature of observer. Media test competency will identify pass or fail criteria, as well as volume, filled units, and interpretation of results.	November 15, 2018
		Monitoring: IV Compounding Committee will review competency documentation and policy to ensure compliance.	November 15, 2018
		Responsibility: Director of Pharmacy	
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). z A Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for handwashing, fingernail cleaning and care, and prohibits jewelry and makeup. The policy restricts personnel from IV compounding with fever or active respiratory infections, severe sunburn, skin rash or open wounds.	October 3, 2018
		All pharmacy Staff and EVS staff educated to Hand Hygiene and Garbing Policy.	October 15, 2018
		A new standard operating procedure has been adopted, Hand Hygiene and Garbing or Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. Pharmacy and EVS Staff will be educated to the new policy.	November 2, 2018 November 16, 2018
		Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4	November 30, 2018

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		weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). aa: Standard Operating Procedure written for Hazardous Drug Employee Training and Safety Program. Six criteria defined using the National Institute for Occupations Safety and Health for definition of a hazardous drug. The policy identifies that IV compounding staff as well as Environmental services personnel will undergo specific hazardous drug training and competency evaluations. IV Compounding Staff and Pharmacy Environmental Services staff have be mandated to complete Hazardous Drug Employee training. Monitoring:] The IV Compounding Committee will review completed competencies on IV Compounding staff and Pharmacy Environmental staff. Responsibility: Director of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). bb: At time of survey, documentation of air exchanges was available but not requested reflecting that the air exchanges exceeded 12 air exchanges per hour. Responsibility: Director of Facilities Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). cc: Volume of primary engineering control (PEC) was available on environmental report at time of survey and	November 2, 2018 November 30, 2018 December 7, 2018 October 3, 2018 October 3, 2018

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		was located near the test result column and was in per liter format. Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). dd Standard Operating Procedures developed: • Airflow Considerations and Pressure Differential Monitoring, • Surface Sampling • Maintenance and Use of Compounding Isolators (CAI's and CACI's) • Non Viable Particle Testing • Viable Air Sampling Quality Management Considerations in Environmental and Personnel Sampling • Pharmacy Compounding Cleaning policy Responsibility: Director of Pharmacy	November 2, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). ee: Hazardous Drug Employee Training and Safety Program standard operating Procedure adopted. The procedure identifies the labeling of hazardous material. All IV compounding staff will be educated to the policy. Monitoring: The IV Compounding Committee will review completed competencies on IV Compounding staff and Pharmacy Environmental staff. Responsibility: Director of Pharmacy	October 18, 2018 November 30, 2018 December 7, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). ff: A Standard Operating Procedure was created for Hand	October 3, 2018

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		Hygiene and Garbing during the survey which specifies that the Garb (bunny suit/gown) and shoe covers must be changed anytime an individual leaves the segregated compounding area and entire hand hygiene and garbing process repeated from the beginning. Bunny suits/low shedding gowns may be re-used during a single work shift if not visibly soiled and not worn outside of the segregated compounding area. Pharmacy and EVS Staff re-educated to policy. A new standard operating procedure has been adopted, Hand Hygiene and Garbing or Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in IV compounding units. Monitoring: IV Compounding staff and EVS will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). gg: Pharmacy Compounding Room/Cleaning Policy specifies that the tacky mat will be changed daily. Environmental staff re-educated to policy. Monitoring: Replacement of the tacky mat will be audited 3 times per week for 4 weeks to ensure that the mat is replaced. Responsibility: General Manager Environmental Services Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). hh: The fatigue mat was removed at time of survey. Monitoring:	October 16, 2018 November 2, 2018 November 30, 2018 October 18, 2018 November 2, 2018 November 30, 2018 October 3, 2018

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		Will audit weekly for one month to ensure that the fatigue mat is not replaced. Responsibility: Manager of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). ii thru kk: Standard Operating Procedure was created for Hand Hygiene and Garbing during the survey which is specifically for IV compounding and describes instructions for handwashing, fingernail cleaning and care, and prohibits jewelry and makeup. The policy restricts personnel from IV compounding with fever or active respiratory infections, severe sunburn, skin rash or open wounds. All pharmacy Staff and EVS educated to Hand Hygiene and Garbing Policy. A new standard operating procedure bas been adopted, Hand Hygiene and Garbing or Non Hazardous Sterile Compounding that standardizes the process of hand hygiene and garbing in compounding units. IV compounding staff and EVS staff will be education to the new policy. Monitoring: IV Compounding staff will be audited for hand hygiene and appropriateness of garbing 3 times per week for 4 weeks. Responsibility: Infection Prevention Specialist Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). II: The fatigue mat was removed at time of survey. Monitoring: Will audit weekly for one month to ensure that the fatigue mat is not replaced.	November 30, 2018 October 3, 2018 October 15, 2018 November 2, 2018 November 16, 2018 November 30, 2018 October 3, 2018 November 30, 2018

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		Responsibility: Manager of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). **mm** IV Compounding Room Infection Control policy was current at time of survey and directs IV compounding staff to visually inspect IV compounding products for the presence of particulate matter and evidence of incompatibility. This policy was not requested at time of survey. Responsibility: Director of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). **nn and oo:** Hospital Multidose/ single dose vial policy was developed in 2001 and was current to date at time of survey. This policy was not requested at time of survey. Policy addressed labeling with expiration date, and product use if worse than ISO Class 5 . Responsibility: Director of Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). **qq** In Process Check Policy written which addresses inspection of all compounding products for particulate matter, bag leakage and change in color. Pharmacy staff educated to policy. Responsibility: Manager Pharmacy Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). **rr:**	October 3, 2018 October 3, 2018 November 2, 2018 November 16, 2018

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		At time of survey, documentation of air exchanges was available but not requested reflecting that the air exchanges exceeded 12 air exchanges per hour. Responsibility: Director of Facilities	October 3, 2018
		Applies to 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6). ss Standard Operating Procedure written for Hazardous Drug Employee Training and Safety Program. Six criteria defined using the National Institute for Occupations Safety and Health for definition of a hazardous drug. The policy identifies that IV compounding staff as well as Environmental services personnel will undergo specific hazardous drug training and competency evaluations. IV Compounding Staff and Pharmacy Environmental Services staff will be mandated to complete Hazardous Drug Employee training.	November 2, 2018 November 30, 2018
		Monitoring: The IV Compounding Committee will review completed competencies on IV Compounding staff and Pharmacy Environmental staff. Responsibility: Director of Pharmacy	December 7, 2018
Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).	1. *Based on the hospital's medical record review, facility policies, documentation and staff interviews, the laboratory director failed to ensure proper oversight of testing personnel to ensure laboratory testing personnel report critical value test results according to established policies and procedures and maintain competency to report critical tests results promptly and proficiently in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements. The findings include:	Applies to 19-13- D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6) 1: Employee TP1, was a new, per diem employee who was terminated for not following hospital policy. TP1, with 13 years of lab experience, was educated to hospital policy and acknowledged through documentation that he was trained, understood the policy and was comfortable with performing critical value reporting. TP1 had previously demonstrated an	August 31, 2018

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	a. Review of hospital root cause analysis and action plan on 9/26/18 for testing performed Sunday 8/5/18 hetween 3:23PM - 6:57PM, Laboratory Technician#1 (LT) questioned Patient #1's abnormally high potassium (K) result of 9.0 mEq/L(normal range for K is 3.5 - 5.1 mEq/L). The K test was automatically repeated hy the chemistry analyzer to auto recheck the validity of the K result. The auto recheck confirmed an abnormally high K result of 9.1 mEq/L. LT #1 cancelled the Basic Metaholic Panel (BMP) order without recording it in the laboratory information system (EPIC) and did not verbally relay the critical result to the unit coordinator (UC), and only requested a redraw. The Surgical Intern realized the first BMP was cancelled at 4:55PM and ordered a 2nd BMP test at 5:12PM which was received in the lab at 5:56PM. At 6:21PM the patient coded and the Registered Nurse (RN) immediately called the lab to inquire about BMP results. LT#1 reported the only available test result, heing Sodium at 134(normal range is 136-145mEq/L). The RN heard "K 3.4" with no read back to verify the accuracy of the result, which was reported to the code team. At 6:51PM LT #1 called the UC to report the K result of 9.5. Patient #1 was pronounced dead at 6:55PM. 1. Lahoratory Technician #1 (LT) failed to follow lahoratory procedures for reporting of critical result values. The laboratory Evaluation of Patient Data policy and procedure (number Chem 22.0) approved on 10/12/17 states a "Fail verify" result that has heen determined to be critical will immediately he called to the healthcare provider and to follow the laboratory procedure of documentation. For an "Absurd Value" an absurd message will be sent when a result is entered that has been defined according to the Min/Max value to he non-compatible. The result must be rerun and verified before heing accepted. 2. Laboratory Technician #1 (LT) failed to follow the hospital Quality Assurance Performance Improvement (QAPI) procedures for reporting critical values. The	understanding of all reporting requirements for critical values and read back responsibilities and TP1 documented all required elements of such as recently as July 14th and 15,th 2018 and recording this information appropriately in the LIS. Critical value policy was updated to reflect that only licensed clinical staff can receive critical value results. All lahoratory staff re-educated to lah critical value policy. Re-education included staff to read and sign acknowledgement of updated policy and all lah technicians were successfully ohserved in performing critical value reporting with read back per policy. This competency will be performed twice annually for a new lab employee and once annually thereafter. Compliance to critical value monitoring to be reported through the Medical Executive Committee and to the Quality Committee of the Board. Monitoring: The Lab Management will audit 10 critical values a week for 4 weeks or longer until 100% compliance is achieved. Monitoring will include ensuring that the critical value is reported hy the lahoratory technician within 30 minutes of resulting in HIS as defined by hospital lab policy, that the critical value is reported to a licensed clinical provider, that a read back is performed and that the critical value is documented in the Sunquest lab system. Responsibility: Director of Lahoratory Services	August 15, 2018 August 30, 2018 October 15, 2018

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	hospital policy "Critical Laboratory Test Results Warranting MD Alerts" effective November 2014 which states "The following test results warrant immediate notification (regardless of the delta checks) to the physician, nurse, or other appropriate health professional within thirty minutes of being completed. After each result has been rechecked by a technologist, he/she will document in the LIS and on the department copy of the report (if applicable) the name of the person(s) notified, date and time called, verification of "read-back" results and the initials of the person making the call. The initials indicate that the person receiving the critical results have read back to the caller the patient's full name and complete results." The above procedure also states that all potassium (K) results over 6.0 mEq/L are critical and the physician, nurse, or other appropriate health professional must be notified. 3. Laboratory Technician #1written statement to the Technical Supervisor (undated) identified Patient #1 was admitted to the emergency room (ER) on 8/5/18. A basic metabolic panel (BMP) along with other tests were ordered and specimen was sent to the lab at 3:59PM on 8/5/18 for testing. A critical 9.1 mEq/L potassium (K) high result value was obtained. Laboratory Technician #1called the ER and directed the Unit Coordinator to recollect the sample due to the sample being questionable and cancelled the BMP test. The critical potassium result value of 9.1 mEq/l was never reported to the Unit Coordinator or entered in the LIS (Laboratory Information System). 4. Review of the patient test report on 9/26/18 for the above specimen sample number X125502 revealed the BMP was deleted with a comment which stated "specimen unsuitable. Please re-order or resubmit. IV fluid contamination." The laboratory information system, (Sunquest), audit system revealed the identification number for the Laboratory Technician who entered the above comment for sample number X125502 was Laboratory Technician #1.		

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	5. Review of the state survey telephone interview with Laboratory Technician #1 on 9/11/18 at 7:55 PM identified the ER was notified on 8/5/18 at 4:56 PM, the test result was questionable and to redraw the patient with no mention of the critical K result. Laboratory Technician #1 further identified he/she wasn't properly trained, was not shown laboratory policies or asked to sign any policies, the critical laboratory procedure was not clear on how to report questionable critical values and that no one had observed Laboratory Technician #1 resulting or reporting critical value results. 6. Review of Laboratory Technician #1 training documentation on 9/26/18 failed to provide evidence of direct observation of reporting critical values however, Laboratory Technician #1 checked the box on the training form that he/she fully understood and felt competent to perform critical Values/Documentation for the Beckman Coulter AU5800 instrument on 5/8/18. The Technical Supervisor signed off Laboratory Technician #1 was fully trained on 5/12/18. 7. Review on 9/26/18 of the state surveyor's interview with the Technical Supervisor on 9/6/18 at 9:45 AM identified Laboratory Technician # 1 failed to follow laboratory procedures for reporting of critical value results. Laboratory Technician # 1 was hired on 3/12/18 and signed training documentation on 5/8/18 indicating he/she was fully competent to perform and report critical value results. Technical Supervisor signed Laboratory Technician #1 training documentation on 5/12/18 and identified once the Technical supervisor signs training documents, staff are considered competent to perform those duties. 8. Interview with the Laboratory Director on 9/26/18 at 4:00PM identified Laboratory Technician #1 failed to follow the hospital QAPI and laboratory policies and procedures for the reporting of critical values and that he/she relies on the Technical Supervisor to train, evaluate and monitor laboratory technicians for pre-analytical, analytical and post-		

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	analytical testing in the laboratory.			
Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).	8. *Based on staff interviews and a review of the hospital's policies and procedures, the hospital failed to have a policy for the administration of anesthesia that was comprehensive and accurate. The finding included: a. Review of the clinical record identified Patient #1 was admitted to the hospital on 7/31/18 with cholecystitis and underwent a laparoscopic cholecystectomy under general anesthesia on 8/1/18. Interview and review of the surgical report with (Certified Registered Nurse Anesthetists) CRNA #1 on 9/25/18 at 2:00 PM identified Patient #1 entered the operating room on 8/1/18 at 12:04 PM. CRNA #1 and MD #1 were present. Anesthesia induction commenced at 12:14 PM with medications that included Versed, Propofol, Fentanyl, and Rocuronium. Patient #1 was intubated at 12:16 PM. CRNA #1 indicated the intubation was difficult with tightness identified around the intubation tube that required further assessments and repositioning. After the intubation was completed by MD #1, who was the anesthesiologist, MD #1 left the room. Shortly after MD #1 left the room, elevated peak pressures were noted, the endotracheal tube (ET) was reevaluated and ventilation settings were adjusted. A surgical time out was then conducted. CRNA #1 indicated she stopped what she was doing to participate in the time out and to verify if antibiotics were administered, as she had not reviewed the medical record prior to the initiation of the case. The surgical incision was made at 12:26 PM. Subsequent to the surgical incision, CRNA #1 identified she assessed the patient's airway with a laryngoscope to ensure placement of the ET tube. Patient #1's blood pressure and heartrate were elevated which was thought to be related to sympathetic stimulus, therefore, Propofol and		Applies to 19-13-D3 ((b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6) 8: Guideline for Administering of Anesthesia policy updated to specify that an "anesthetist" must be in the room at all time during anesthesia administration. All staff were re-educated to policy that an Anesthesiologist will be present in room throughout the induction and the administration of gas. Monitoring: Audit of 5 records per week for 6 weeks or until 100% compliance is achieved. Responsibility: Department Chair of Anesthesia	August 22, 2018 October 15, 2018

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	Diludid were administered. CRNA #1 indicated almost immediately thereafter it was identified that Patient #1 was breathing over the ventilator which triggered CRNA #1 to check the vaporizer. CRNA #1 realized the Sevoflourine gas had not been turned on for approximately nineteen minutes from the time of the incision. CRNA #1 immediately administered the Sevoflurane (inhalation anesthetic) for the remainder of the case. Subsequent to the procedure, the patient was able to verbalize explicit details of the case and complained of pain during part of the procedure. Further interview with CRNA #1 indicated she was not originally scheduled to provide anesthesia in this case. CRNA #1 identified she had not set up the room and did not have time to review the medical record as was her routine practice. CRNA #1 indicated she should have stopped the line prior to the surgical time out and asked for MD #1 to return to the room to assist in troubleshooting the ventilator, ensure the ET tube placement and overall assessment of the patient prior to the surgical incision. Interview with MD # 1 on 9/25/18 at 3:00 PM identified he was present for the induction and intubation of Patient #1 however, did not ensure that the Sevoflurane was on prior to leaving the room. Interview with the Chief of Anesthesia on 9/25/18 at 1:00 PM identified although the CRNA's administered the Sevoflurane, it was the responsibility of the physician to ensure the Sevoflurane was turned on prior to leaving the room. Further interview and review of the hospital policy entitled Guidelines for Administration of Anesthesia with the Chief of Anesthesia directed in part that an Anesthesiologist or CRNA would be present at the induction of each anesthetic and that all anesthetics initiated by a member of the		

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	Department of Anesthesia required the presence of an attending anesthesiologist throughout the administration of general anesthesia. The Chief of Anesthesia indicated the policy was inaccurate and would be changed to identify that an attending anesthesiologist would be present for the induction of each anesthetic when the case was assigned to a CRNA and that either an anesthesiologist or CRNA would be present throughout the duration of general anesthesia. Subsequent to the incident education was provided to all attending anesthesiologists that indicated the anesthesiologist would be responsible to ensure that he/she was present for induction, intubation, and to verify the anesthetic gas had been turned on prior to leaving the room. The attestation would be recorded in each clinical record.			
Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).	9. *Based on a clinical record review, staff interviews and a review of hospital documentation for one of ten patient's (Patient #1), reviewed for the administration of general anesthesia, the hospital failed to ensure that anesthesia policies addressed pre-anesthesia responsibilities for administering inhalational anesthetic throughout the surgical procedure which subsquently rendered intraoperative awareness and discomfort to the patient. The finding included: a. Review of the clinical record identified Patient #1 was admitted to the hospital on 7/31/18 with cholecystitis and underwent a laparoscopic cholecystectomy under general anesthesia on 8/1/18. Interview and review of the surgical report with CRNA #1 on 9/25/18 at 2:00 PM identified Patient #1 entered the operating room on 8/1/18 at 12:04 PM. CRNA #1 and MD #1 were present. Anesthesia induction commenced at 12:14 PM with medications that included Versed, Propofol, Fentanyl, and Rocuronium. Patient #1 was intubated at 12:16 PM. CRNA #1 indicated the intubation was difficult with		Applies to 19-13-D3 ((b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6) 9: Guideline for Administering of Anesthesia policy updated to specify that an "anesthetist" must be in the room at all time during anesthesia administration. All staff were re-educated to policy that an Anesthesiologist will be present in room throughout the induction and the administration of gas. Monitoring: Audit of 5 records per week for 6 weeks or until 100% compliance is achieved. Responsibility: Department Chair of Anesthesia	August 22, 2018 October 15, 2018

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	tightness identified around the intubation tube that required further assessments and repositioning. After the intubation was completed MD #1, who was the anesthesiologist, left the room. Shortly after MD #1 left the room elevated peak pressures were noted, the endotracheal tube (ET) was reevaluated and ventilation settings were adjusted. A surgical time out was then conducted. CRNA #1 indicated she stopped what she was doing to participate in the time out and to verify if antibiotics were administered, as she had not reviewed the medical record prior to the initiation of the case. The surgical incision was made at 12:26 PM. Subsequent to the surgical incision - CRNA #1 identified she assessed the patient's airway with a laryngoscope to ensure placement of the ET tube. Patient #1's blood pressure and heartrate were elevated which was thought to be a result of sympathetic stimulus, therefore, Propofol and Diludid were administered. CRNA #1 indicated almost immediately thereafter, it was identified that Patient #1 was breathing over the ventilator which triggered CRNA #1 to check the vaporizer. CRNA #1 realized the Sevoflourine gas had not been turned on for approximately nineteen minutes from the time of the incision. CRNA #1 immediately administered the Sevoflurane for the remainder of the case. Subsequent to the procedure the patient was able to verbalize explicit details of the case and complained of pain during part of the procedure. Further interview with CRNA #1 indicated she was not originally scheduled to provide anesthesia in this case. CRNA #1 identified she bad not set up the room, and did not have time to review the medical record as was her rountine practice. CRNA #1 indicated she should have stopped the line prior to the surgical time out and asked for MD #1 to return to the room to assist in troubleshooting the ventilator, ensure the ET tube placement and overall assessment of the patient prior to the surgical incision.			

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	Interview with MD #1 on 9/25/18 at 3:00 PM identified he was present for the induction and intubation of Patient #1 however did not ensure that the Sevoflurane was on prior to leaving the room. Interview with the Chief of Anesthesia on 9/25/18 at 1:00 PM identified although the CRNA's administered the Sevoflurane it was the responsibility of the physician to ensure the Sevoflurane was turned on prior to leaving the room. Subsequent to the incident, education was provided to all attending anesthesiologists that indicated that the anesthesiologist would be responsible to ensure that he/she was present for induction, intubation, and to verify the anesthetic gas had been turned on prior to leaving the room. The attestation would be recorded in each clinical record.			
Section 19-13-D3 (b) Administration (2) and/or (i) General (6).	10. Based on a review of facility documentation, interviews and policy review, the facility failed to ensure that quality services were rendered by a contracted service. The findings include the following: a. Review of the Reverse Osmosis (RO) logs for RO #6 for the month of October indicated that on 10/12/18, RN #109 documented that the Chlorine level was 0.2 parts per million (normal less than 0.1 ppm) at 7:40 AM and again at 2:55 PM. Review of the log and interview with the Clinical Service Specialist (CSS) on 11/15/18 at 9:30 AM stated that RN #109 incorrectly documented the results and should have been 0.02 ppm. The CSS identified that if the result was 0.2 ppm, patients would have experienced an adverse outcome and no patients have. Although the CSS stated she reviews the logs, the error was not identfied until the surveyor inquired about the abnormal results. b. Review of training education failed to reflect that RN #109 had been educated on water testing. Interview with the Manager on 11/15/18 at 10:00 AM indicated		Applies to 19-13-D3 (b) Administration (2) and/or (i) General (6) 10a: The dialysis unit utilized two different Reverse Osmosis (RO) machines. The dialysis unit standardized to one WRO300 machine type and stream lined the RO daily log to adhere to the parameters specifically to the WRO300 machine. The dialysis staff was re-educated on the appropriate identification of water quality checks and how to appropriately document on the RO log. The dialysis staff documentation was validated with return demonstration and skill verification. Monitoring: The dialysis management team will audit the RO log documentation one time per week for 8 weeks to ensure accurate documentation of quality water checks including chlorine levels and pressures. Responsibility: Director of Davita Dialysis	December 1, 2018 November 16, 2018 November 16, 2018 January 11, 2019

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	RN #109 was an orientee and had not completed water monitoring education. c. Review of the reverse osmosis logs for machine #7 for the period of 10/1/18 through 10/26/18 indicated that the normal parameters for RO pressures was 180-200 PSI. Review of the log indicated results of not applicable (n/a) and/or, 170 psi and values 1000-1290. Review of the log with the Biomedical Manager indicated that machine #7 does not have the capability to display the RO pressures and that the log being used was incorrect and it was unclear where staff could be getting the results documented. Subsequent to inquiry, the log was switched to reflect the appropriate monitoring that is required. Review of the policy indicated only teammates who have been trained to perform the observations and testing required will be permitted to test and document their findings on a water treatment log. On 11/15/19, the hospital provided the Department with an immediate action plan that identfied all staff will be reeducated on water testing and documentation of logs (RO start-up log).	Applies to 19-13-D3 (b) Administration (2) and/or (i) General (6) 10b: RN#109 received water monitoring education. All new dialysis employees will have their full orientation education completed prior to the start date. Oversight of the new hire documentation and annual competencies for current staff will be given to the hospital's dialysis nurse liaison Monitoring: Review of the dialysis unit staff will be reviewed monthly to ensure that all new orientees have had their full orientation Responsible Person: Dialysis Nurse Liaison Applies to 19-13-D3 (b) Administration (2) and/or (i) General (6) 10c: The dialysis unit utilized two different Reverse Osmosis (RO) machines. The dialysis unit standardized to one WRO300 machine type and stream lined the RO daily log to adhere to the parameters specifically to the WRO300 machine. The dialysis staff was re-educated on the appropriate identification of water quality checks and how to appropriately document on the RO log. The dialysis staff documentation was validated with return demonstration and skill verification. Monitoring: The dialysis management team audited RO log documentation one time per week for 8 weeks to ensure accurate documentation of quality water checks including chlorine levels and pressures. Responsibility:	November 16, 2018 December 31, 2019 December 1, 2018 November 16, 2018 November 16, 2018 January 11, 201

		STATEMENT OF VIOLATIONS	Date of Inspection:
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		Director of Davita Dialysis	
Section 19-13-D3 (b) Administration (2) and/or (i) General (6).	11. *Based on observations, documentation review and interviews, the hospital failed to ensure that the psychiatric environment was monitored to ensure patient safety while identified ligature risks were present in the environment. The findings include: a. Tour of the in-patient psychiatric unit was conducted on 11/8/18 at 10:00 AM. Observations identified 3 medical beds with cranks and side rails in use and 8 patient bathroom doors with hinges not designed for the psychiatric environment, and posed a ligature risk. The hospital's ligature risk prevention project documentation updated on 11/5/18 was reviewed with the VP of Administration and COO on 11/8/18. The project documentation identified in part that the psychiatric unit had bathroom door hinges that required remediation. It was identified that replacement hinges were on back order from the manufacturer. Interview with MHW #1 on 11/8/18 at 10:20 AM identified that she was not aware of which bedrooms on the unit had bathrooms with hinges that posed a ligature risk. Interview with the Director of Psychiatry on 11/8/18 at 10:25 AM identified that he was not aware of which bedrooms on the unit had bathrooms with hinges that posed a ligature risk, and was unaware of which patient bedrooms had medical beds with cranks and side rails. The Director identified that Staff monitored patients by conducting routine every 15 minutes checks and if a patient was experiencing suicidal ideations, he/she would be moved to a room close to the nurses' station. The Director identified that there was no additional safety monitoring for ligature risks in the psychiatric environment. Subsequently, the hospital developed an	Applies to 19-13-D3 (b) Administration (2) and/or (i) General (6) 11:. Risk Mitigation Policy updated to reflect areas that have been mitigated for ligature Risk; i.e. ceilings, exhaust covers, door stops, sink installation. Behavioral Health staff educated to the updated policy and reinforced with staff areas under Q15 environmental checks requiring ligature risk review; i.e door hinges, door top alarms. The environmental checks are in addition to the current Q15 minute patient safety checks. The environmental and patient safety checks are documented. Two ligature resistant medical beds have been purchased through Sizewize. These beds are ligature resistant in design, are controlled electrically through nursing lockout controls, and are designed with contiguous molding that provides secure wiring. Staff have been instructed on the use of these ligature resistant medical beds. Door hinges and door alarms received and are in process of being installed. Planned date of completion is January 30, 2019 concluding all areas of identified ligature risk. Monitoring: Environmental and Patient safety checks every 15 minutes are documented using a checklist identifying all areas of risk in the behavioral health unit. Continued ligature risk assessments will be monitored through Environment of care rounding as scheduled using a ligature assessment tool and every 6 months during a ligature risk focus assessment. Responsible Person: Regional VP of Behavioral Health	January 3, 2019 & January 22, 2019 December 19, 2018 January 12, 2019 January 30, 2019 January 30, 2019

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	environmental monitoring plan to ensure the safety of patients while ligature risks existed on the psychiatric unit. On 11/5/18 at the time of the tour, the unit census was 12 and there were no patients with current suicidal ideations.		
Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1).	12. Based on clinical record review, interviews and policy review for 1 of 3 sampled patients a. Patient #164 was admitted on 7/7/18 due to mood liability after a discontinuation of medications and paranoia. Nursing progress notes dated 7/8/18 at 1:30AM identified Patient #164 was increasing psychotic, loud screaming, darting in and out of patient rooms, disoriented, and multiple attempts to hit staff. The note identified the physician was made aware and directed to place the patient in 4 point restraints, STAT medications were administered and the restraint protocol was initiated. Review of the non-violent restraint order dated 7/8/18 at 1:41AM identified physical restraints is medically necessary to maintain patient safety. Review of the restraint monitoring form dated 7/8/18 at 1:30AM identified the patient was in four (4) point restraints from 1:30AM through 5:45AM (a total of 4 hours and 15 minutes). The nursing staff failed to document the patient's assessed behaviors on the monitoring form every fifteen minutes from 1:45AM until 3:00AM (a total of 1 hour and 15 minutes). Additionally, from 3:00AM through 5:45AM staff failed to assess/document behaviors necessitating the continued use of the 4 point restraints. Interview and review of Patient #164 clinical record with the VP of Behavioral Health on 11/15/18 at 11:00AM failed to identify that behaviors were assessed/documented from 1:45AM until 3:00AM, and should have been. Interview with the Director of Regulatory Affairs stated that per policy the behaviors the patient is exhibiting at the time of assessment need to be	Applies to : 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) 12: All OB1 clinical staff re-educated on the application of applying restraints and management of aggressive behavior (CPI) training; including identifying the type of least restrictive restraint, the documentation of behaviors of the patient in restraint and the earliest removal of the restraint based on behaviors. All staff were required to physically demonstrate competency of restraint application. Reporting of behavioral health restraint usage is a key performance indicator on the unit and is reported monthly at the Behavioral Health Quality Committee. Behavioral Health restraints is integrated into the hospitals QAPI program. Monitoring: All behavioral health unit restraints are audited to ensure compliance of documentation of least restrictive type of restraint utilized, the earliest release of the restraint and appropriate behaviors requiring the restraint. Responsibility: Regional Vice President of Behavioral Health	December 15, 2018 Indefinite

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	descriptive to identify the appropriate use of 4 point restraints. Facility policy for restraints identified the use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment of the patients compliance with the established behavioral criteria and reevaluation of the patients condition.		
Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1).	13. Based on clinical record review, interviews and policy review for 1 of 3 sampled patients a. Patient #164 was admitted on 7/7/18 due to mood liability after a discontinuation of medications and paranoia. Nursing progress notes dated 7/8/18 at 1:30AM identified Patient #164 was increasing psychotic, loud screaming, darting in and out of patient rooms, disoriented, and multiple attempts to hit staff. The note identified the physician was made aware and directed to place the patient in 4 point restraints, STAT medications were administered and the restraint protocol was initiated. Review of the non-violent restraint order dated 7/8/18 at 1:41AM identified physical restraints is medically necessary to maintain patient safety. Review of the restraint monitoring form dated 7/8/18 at 1:30AM identified the patient was in four (4) point restraints from 1:30AM through 5:45AM (a total of 4 hours and 15 minutes). The nursing staff failed to document the patient's assessed behaviors on the monitoring form every fifteen minutes from 1:45AM until 3:00AM (a total of 1 hour and 15 minutes). Additionally, from 3:00AM through 5:45AM staff failed to assess/document behaviors necessitating the continued use of the 4 point restraints. Interview and review of Patient # 164 clinical record with the VP of Behavioral Health on 11/15/18 at 11:00AM failed to identify that behaviors were assessed/documented from 1:45AM until 3:00AM, and should have been.	Applies to 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) 13: All OB1 clinical staff re-educated on the application of applying restraints and management of aggressive behaviors (CPI) training; including identifying the type of least restrictive restraint, the documentation of behaviors of the patient in restraint and the earliest removal of the restraint based on behaviors. All staff were required to physically demonstrate competency of restraint application. Reporting of behavioral health restraint usage is a key performance indicator on the unit and is reported monthly at the Behavioral Health Quality Committee. Behavioral Health restraints is integrated into the hospitals QAPI program.. Monitoring: All behavioral health unit restraints are audited to ensure compliance of documentation of least restrictive type of restraint utilized, the earliest release of the restraint and appropriate behaviors requiring the restraint. Responsibility: Regional Vice President of Behavioral Health	December 15, 2018 Indefinite

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Saint Mary's Hospital	56 Franklin Street, Waterbury, Connecticut 06706		
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	Interview with the Director of Regulatory Affairs stated that per policy the behaviors the patient is exhibiting at the time of assessment need to be descriptive to identify the appropriate use of 4 point restraints. Facility policy for restraints identified the patient is checked every fifteen (15) minutes by qualified staff whether the patient continues to exhibit the behavior indicating a need for a restraint.		
Section 19-13-D3 (b) Administration (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).	14. *Based on clinical record review, review of hospital policies and interviews with staff for 3 of 6 patients undergoing procedures (Patients #120, 121 & 122) the hospital failed to ensure that a time-out was performed accurately resulting in a wrong site biopsy and/or failed to ensure that procedural objects were accounted for resulting in retained objects. The findings include: a. Patient #120 was admitted on 9/7/17 for an ultrasound-guided left thyroid node biopsy. According to the procedural note, the correct side, site and patient position were verified. Following the time-out MD#106 performed a right thyroid node biopsy in error. Patient #120 was informed of the error and the left node biopsy was then performed. Interview with MD #106 on 11/16/18 at 9:30 AM identified that he was aware that the procedure was to be done on the left side, he performed the procedure on the right side in error. Interview with the Quality Manager on 11/16/18 at 9:20 AM, review of the hospital's time-out policy and review of the hospital's corrective action plan identified that despite performing the time-out, MD #106 performed the procedure on the incorrect site. Following this incident, staff were re-educated on the time-out policy. b. Patient #121 was admitted on 9/21/18 and	Applies to 19-13-D3 (b) Administration (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6). a: The Radiology Department, including all nurses, physicians and applicable radiological technologists were re-educated to the hospitals time-out policy. The time out process education stressed attention to detail and focusing on just the procedure without distraction. Monitoring: Audited of 5 charts per week for 16 weeks to ensure compliance with the time-out process in Radiology for all ultrasound guided procedures was conducted. Responsibility: Director of Imaging Services Applies to 19-13-D3 (b) Administration (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6). b:	November 30, 2017, February 28, 2017

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	underwent an open ventral hernia repair. Prior to leaving the operating room, a urinary catheter was inserted by RN #101. The patient was discharged home on 9/24/18. On post-operative day #5 Patient #121 identified having pelvic pain, odor and a foreign body was found in the patient's vagina. Patient #121 notified the physician who identified that an image of the foreign body was that of a perineal swap stick used during the insertion of the urinary catheter on 9/21/18. Interview with RN #101 on 11/15/18 at 10:05 AM identified that the perineal swab stick was inserted into the patient's vagina to use as a guide for the urinary catheter insertion. RN #1 identified that it was a practice learned in nursing school. RN #101 identified that she no longer uses this practice when inserting urinary catheters. Interview with Quality Staff #1 on 11/15/18 at 11:15 AM, review of the hospital's urinary catheter insertion policy and review of the hospital's corrective action plan identified that RN #101 did not follow the hospital policy for urinary catheter insertion and the swab stick should not have been inserted in the vagina. Following this incident, staff were re-educated on the urinary catheter insertion policy.	Immediate action taken by Director of Surgical Services and the Chairman of Surgery to cease and desist the practice of inserting a perineal swab stick into the vagina during urinary catheter insertion for all staff. A practice alert was shared with all clinical unit managers to ensure that this practice was stopped in all clinical units. HealthStream education and assessment test assigned to all Operating Room nurses, completed. Mandatory hands on skill station completed so that Operating Room nurses demonstrated proper foley insertion. Mandatory hands on skill station completed for PACU and SDS nursing staff. Monitoring: 10 foley insertions a month for 3 months will be audited in SDS and OR to ensure proper foley insertion. Responsibility: Director of Surgical Services	October 4, 2018 October 5, 2018 October 31, 2018 October 16, 2018 October 18, 2018 January 21, 2019
c.	Patient #122 was admitted on 5/22/18 with a diagnosis of sigmoid colon adenocarcinoma and underwent an open low anterior resection and lysis of adhesions. According to the surgical record, all sponge counts were correct at the conclusion of the surgery. Patient #122's post-operative stay was uncomplicated and was discharged on 5/30/18. Patient #122 returned to the hospital on 8/31/18 after experiencing a lump on the abdomen that was identified as a foreign body. The foreign body was surgically removed and identified as a retained surgical sponge. Interview with MD #105 on 11/15/18 at identified	Applies to 19-13-D3 (b) Administration (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6). c: Sponge count policy was reviewed and revised according to AORN standards. The policy was revised so that the counting of sponges is done from bottom to top and left to right within the sponge counting bag system to allow for better visualization of an error. Surgical Staff re-educated to policy. Surgical Medical Staff educated to revised policy at Surgical Section Meeting. White boards hung and utilized to add a visual cue of the count process.	August 22, 2018 August 31, 2018 October 1, 2018 August 31, 2018

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	that at the conclusion of Patient #122's surgery counts were verified as correct twice and he had no reason to suspect otherwise. Interview with Quality Staff #1 on 11/15/18 at 11:00 AM, review of the hospital's sponge count policy and review of the hospital's corrective action plan identified that despite performing and documenting that sponge counts were correct, a sponge was retained. Following this incident, staff were re-educated on the surgical count process.	Monitoring: 18 audits were completed for one month to ensure sponge count was performed per policy. The observation of the count process before, during, after and at change of shifts was performed for each audit. Responsibility: Director of Surgical Services	October 31, 2018
Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and/or (i) General (6).	15. *Based on clinical record review, interview and policy review for 1 of 4 patients (Patient #118) the facility failed to ensure that a patient did not receive a medication that he/she had a documented allergy to. The findings include the following: a. Patient #118 was admitted on 2/19/17 at 2:16 PM with a urinary tract infection. The patient had a history of seizure disorder, cerebral palsy and generalized epileptic syndrome. The nursing note at 7:03 PM indicated that an allergy band was in place. Review of the record with the quality coordinator on 11/14/18 at 1:30 PM indicated that the record reflected that the patient had an allergy to Rocephin. The record indicated that on 2/19/17 at 9:35 PM MD #107 directed Ceftriaxone 1 gram intravenous times 1, which was administered as directed. A note at 9:45 PM indicated that the patient had an allergic reaction to the Ceftriaxone and had swelling to lips and eyes. The patient was given stat Benadryl and Epinephrine with good effect. The note indicted that the patient did have a documented allergy in the chart. Interview with the Quality Coordinator in 11/14/18 at 1:30 PM indicated that the allergy was documented in the computer by the triage nurse however was not confirmed. This missing step resulted in the allergy not being linked in the system	Applies to 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and/or (i) General (6). A modification had been created in the electronic health record requiring that the triage staff acknowledge and confirm patient allergies to allow for advisory alerts to be generated notifying the provider of any allergies. In the event that the triage nurse cannot confirm allergies (due to the patient's condition) it is the responsibility of the patient's provider and primary nurse. The Emergency Services staff including nurses, physicians staff and pharmacy technicians were re-educated on how to confirm allergies in the electronic health record. New electronic health record (EPIC) installed. An allergy warning is triggered when an attempt to order contradictory medication is entered. Also, the physician, nurse and pharmacist receive advisory alerts when allergies are not documented in the medical record. A physician/RN/ Pharmacist must enter a reason for overriding warning. Monitoring: An audit of 4 charts per week for 3 months was conducted to ensure that allergies were documented, confirmed and acknowledged. Current audit of 50 ED charts showed 100% compliance with allergy documentation.	March 31, 2017 April 13, 2017 & April 4, 2017 July 1, 2017 June 30. 2017 January 4, 2019

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	to identify drug interactions/allergy's. The Quality Coordinator indicated that the allergy was still visible on the home page of the computerized medical record screen. Following the incident, staff were reeducated and quality monitoring was initiated. In addition, the hospital had changed to a new computer system. MD #107 was unavailable for interview. The facility failed to ensure that MD# 107 reviewed the patient's allergies prior to ordering a medication and/or that RN #107 reviewed the patient's allergies prior to the administration of the medication.	Responsibility: Manager of Emergency Services	
Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).	16. Based on clinical record review, interview and policy review for one patient (Patient #107) the facility failed to ensure that a physician assessment was conducted and/or documented. The findings include the following: a. Patient #107 was admitted on 4/11/17 for a laparoscopic cholecystectomy. A nursing pre-operative assessment identified a blood pressure of 129/76. A preoperative anesthesia assessment identified the patient's blood pressure as 129/72 at 7:15 AM. The patient arrived in PACU at 8:36 AM with a pain scale of 0/10 (10 worst) and a pain of 10/10 at 8:56 AM. Patient #107 received IV anxiolytic and pain medications. Pain at 9:35 was 4/10 and at 10:42 AM was 10/10. Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was completed at 10:35 AM for post-operative analgesia. The anesthesia record identified the patient's blood pressure was 93/59, heart rate was 68, the patient was sedated, following commands, stable and tolerated the procedure well. Pain score was 3/10 post procedure at 10:46 AM. Nursing notes dated 4/11/17 at 10:56 AM identified	Applies to 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3). A new policy was put into place which addressed the requirement that a progress note is to be written immediately by the physician/provider in the patient's medical record for any patient experiencing a significant change in their clinical condition. The policy lists 9 examples of conditions that would require an immediate progress note. Currently, the Bylaws had addressed that a progress note was to be written "daily". Change in Patient's Condition policy was communicated to the Medical and Surgical Residents and all members of the credentialed medical staff. All new providers applying for privileges at Saint Mary's Hospital will also attest to their acknowledgement of the policy. Monitoring: An audit 5 patient records per week for 4 weeks to ensure that all physician notes are present and timely, specifically for patients with a significant change in their clinical condition. Non-compliance will be addressed by the Department	January 3, 2019 January 5, 2019 January 31, 2019

	that Patient #107 was fully awake, out of bed to the bathroom, felt dizzy and faint, and had a blood pressure of 77/44. The physician was notified and 1 liter of lactated ringers was administered. A blood pressure recheck was 96/53. Patient stated he/she felt better with no further dizziness or feeling faint. Review of nursing post-operative vital signs indicated that the patient's BP remained at "+/- 20 pre-op" or within 20mm Hg of pre-anesthetic systolic level for a high of 149 to a low of 109 at 10:00 and 10:56 despite documented blood pressures of 93/59 and 96/53 respectively. According to a nurses note dated 4/11/17 at 10:48 AM a physician was in to assess the patient. However, the clinical record failed to reflect a documented assessment by the physician. Patient #107 was discharged per post-anesthesia protocol at 2:00 PM with discharge instructions. Interview with the Quality Specialist on 11/16/18 at 10:00 AM indicated that when the case was reviewed it was determined that the surgical resident was notified of the patients dropping blood pressure, saw the patient, ordered IV fluids and asked to be called after the fluids were administered however failed to write a note. Review of the medical staff bylaws indicated that progress notes content shall be sufficient information to permit continuity of care.	Chairman. Responsible Person: Director of Regulatory and Medical Staff Affairs	

STATEMENT OF VIOLATIONS		Date of Inspection:
Saint Mary's Hospital	56 Franklin Street, Waterbury, Connecticut 06706	

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Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).	17. *Based on clinical record review, review of hospital policies and interviews with staff for 1 of 6 patients undergoing procedures (Patients #121) the hospital failed to ensure that nursing staff performed a urinary catheterazation per policy and failed to ensure all supplies were accounted for resulting in a retained object. The findings include: a. Patient #121 was admitted on 9/21/18 and underwent an open ventral hernia repair. Prior to leaving the operating room, a urinary catheter was inserted by RN #101. The patient was discharged home on 9/24/18. On post-operative day #5 Patient #121 identified having pelvic pain, odor and a foreign body was found in the patient's vagina. Patient #121 notified the physician who identified that an image of the foreign body was that of a perineal swap stick used during the insertion of the urinary catheter on 9/21/18. Interview with RN #101 on 11/15/18 at 10:05 AM identified that the perineal swab stick was inserted into the patient's vagina to use as a guide for the urinary catheter insertion. RN #1 identified that it was a practice learned in nursing school. RN #101 identified that she no longer uses this practice when inserting urinary catheters. Interview with Quality Staff #1 on 11/15/18 at 11:15 AM, review of the hospital's urinary catheter insertion policy and review of the hospital's corrective action plan identified that RN #101 did not follow the hospital policy for urinary catheter insertion and the swab stick should not have been inserted in the vagina. Following this incident, staff were re-educated on the urinary catheter insertion policy.	Applies to 19-13-D3 (e) Nursing Service (1) and/or (i) General (6). Immediate action taken by Director of Surgical Services and the Chairman of Surgery to cease and desist the practice of inserting a perineal swab stick into the vagina during urinary catheter insertion for all staff. A practice alert was shared with all clinical unit managers to ensure that this practice was stopped in all clinical units. A HealthStream education and assessment test assigned to all Operating Room nurses, completed. Mandatory hands on skill station completed so that Operating Room nurses demonstrated proper foley insertion. Mandatory hands on skill station. completed for PACU and SDS nursing staff. Monitoring: 10 foley insertions a month for 3 months in the OR, SDS and PAUC were audited to ensure proper foley insertion. Responsibility: Director of Surgical Services	October 4, 2018 October 5, 2018 October 31, 2018 October 16, 2018 October 18, 2018 January 21, 2019

		STATEMENT OF VIOLATIONS	Date of Inspection:
Saint Mary's Hospital	56 Franklin Street, Waterbury, Connecticut 06706		
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Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).	18. Based on clinical record review, interview and review of the guidelines for 1 of 3 patients (Patient #131) reviewed the facility failed to ensure that CIWA documentation was completed correctly. The findings include the following: a. Patient #131 was admitted on 11/6/18 with alcohol abuse, pancreatitis and suicidal ideation. The record indicated that the physician directed that the patient was to be monitored via the CIWA protocol. Review of the monitoring indicated that on 11/7/18 at 8:00 AM the patient was scored at 8. The patient was next assessed at 5:40 PM, when the patient was assessed at a 15. The guidelines indicated that the patient should be assessed every four hours for a score of 8-15.	Applies to 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6). All nursing staff re-educated to the CIWA protocol including the timeliness of assessments/reassessments. Education will stress the overview of the CIWA protocol and the compliance with the timely reassessments per CIWA scoring. This education will be in person. A daily CIWA report will be created to identify patients on the CIWA protocol to assist clinical managers on identifying CIWA patients and to assist in appropriate real time documentation. appropriate documentation of CIWA. Monitoring: All patients on CIWA protocol will be monitored daily for 6 weeks to ensure protocol assessments/reassessments. Responsibility: Director of Professional Practice	February 15, 2019 February 15, 2019 March 29, 2019
Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).	19. Based on clinical record review and interview the facility failed to ensure that daily weights were monitored. The finding includes the following: a. Patient #132 was admitted on 11/3/18 with congestive heart failure, and the physician orders directed daily weights. Review of the clinical record with the Manager on 11/13/18 at 10:30 AM indicated that daily weights were completed on 11/3/18 and 11/5/18. The record failed to reflect that daily weights were completed.	Applies to 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1). All nursing staff and certified nurse assistants will be re-educated on the necessity to document a daily weight when an order is present in the patient's medical record. To assist the clinical nurse managers in identifying those patients with physician orders for daily weight documentation, a report will be created in EPIC that will be provided daily for the nurse managers to review to determine which patients with daily weight orders need documentation of daily weights. Monitoring: Will audit 5 patients per week for 4 weeks to ensure	February 15, 2019 February 15, 2019 January 31, 2019

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		daily weights are documented. Responsibility: Director of Professional Practice	
Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).	20. *Based on clinical record review, interview and policy review the facility failed to ensure that 1of 6 post-operative patients were monitored for pain and/or stability. The findings include the following: Patient #107 was admitted on 4/11/17 at 12:30 PM for a laporscopic cholecystectomy. Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was performed at 10:18 AM and completed at 10:35 AM. a. Review of the post -operative vital signs indicated that the patient's BP pre procedure was 148/100. During the peocedure that patients BP's were was 112-120 /70-80's. The record indicated that at 10:25 AM the patient's BP was 120/76. Review of the clinical record indicated that the patient arrived in same day surgery at approximately 10:56 AM on 4/11/17, the patient had a BP of 94/54, pain level of 5 and was fully awake. The record indicated that Percocet 1 tablet was adminsitered at 11:00 AM. The record failed reflect further monitoring of the patients level of pain after 10:56 AM and/or prior to discharge. b. Review of the clinical record indicated that the patient arrived in same day surgery at approximately 10:56 AM on 4/11/17, the patient had a BP of 94/54. The patient's BP at 11:55 AM was 91/58 and at 12:55 PM had a BP 77/45, pulse 73 and respirations 16. The nurse's note indicated that the patient was out of bed to the bathroom felt dizzy and faint, the physician was notified and 1 liter of lactated ringers was administered and blood pressure was rechecked at 1:55 PM and was 96/53. The clinical record	Applies to 19-13-D3 Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6) a , b, c: Computer system (EPIC) updated to include a hardstop for postop pain and vitals assessment for Same Day Surgery (SDS) and Post Anesthesia Care Unit (PACU). OR Discharge Criteria policy updated to reflect that all of the patients' vitals must be within 20% of their baseline. All nursing staff in SDS and PACU were re-educated to the Discharge Criteria policy. Monitoring: Monitored 5 SDS and OR charts per week for 4 weeks to ensure that vitals and pain assessments were documented as appropriate. Responsibility: Director of Surgical Services	November 18, 2018 November 30, 2018 December 31, 2018

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	indicated that the patient was discharged at 2:00 PM absent further rechecks of the patients blood pressure. The record failed to reflect the patients ambualtory status at discharge, pain level and/or that the patients BP was not +/- 20 Hq mm at discharge. Interview with MD # 113 indicated that he was not aware of the patient's change in condition and/or low BP. MD #113 indicated that he would have kept the patient for more monitoring and would have drawn a blood count. Review of the same day surgery criteria indicated that on discharge in part the patient's should have pain score at rest equal to or lower than 4, BP +/- 20 Hq mm of pre procedure range and ambulate with minimal assist. c. Review of the ED record dated 4/11/17 at 8:03 PM identified that within 6 hours of discharge, Patient #107 arrived unresponsive with a systolic blood pressure of 80 per EMS and was 60/40 on arrival to the ED. After arrival to the ED, Patient #107 was responsive and complaining of abdoninal pain. Differential diagnoses included post-operative complication, ruptured viscus, solid organ injury and vascular injury. An abdominal CT scan was completed that indicated the patient had an acute large hemoperitoneum and small pneumoperitoneum is presumably post-operative rather than a perforated viscus. The patient required IV resuscitation, 2 units of blood, ICU monitoring, condition improved and was discharged on 4/15/17.			

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Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).	21. Based on a review of clinical records, interviews, and policy and/or procedure checklists, for 2 of 2 patients reviewed for augmentation of labor, (Patient #160 and #157), the facility failed to ensure the Pre-Oxytocin checklist was completed prior to administration of Oxytocin. The findings include the following: a. Review of the clinical record identified Patient #160 was admitted to the hospital on 11/18/18 with contractions at 41 weeks gestation. The History & Physical (H&P) dated 11/18/18 at 6:02 AM noted a category I (normal) fetal tracing was identified, cervix ripe per RN exam, and consider induction if strong, regular contractions do not recur spontaneously. A Physician's order dated 11/18/18 at 9:46 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. At 9:58 AM, Oxytocin was administered at one (1) milliunit/minute intravenously, increased to 3 milliunits/minute at 10:30 AM, increased to 5 milliunits/minute at 11:00 AM, and then discontinued at 11:38 AM. The patient had a spontaneous vaginal delivery at 12:00 PM. Review of the Pre-Oxytocin checklist, the clinical record, and interview with the Nurse Manager on 11/19/18 at 2:00 PM failed to provide evidence that indication for induction was documented prior to the administration of Oxytocin, that the patient's pelvis was documented to be clinically adequate (should be on prenatal record), failed to document the estimated fetal weight within the past week, that general consent was signed, that the patient's cervix was assessed and documented immediately prior to induction (lack of documentation that a practitioner performed within four hours of induction), and/or that the presentation was assessed and documented. Review of the Pre-Oxytocin checklist directed that	Applies to 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6) OBGyn physicians and CNM's educated regarding the necessity to document adequate pelvic & cervical exam and estimated fetal weight prior to the nurse proceeding with Pitocin administration. Women and Infants Nursing staff will be instructed to not administer Pitocin unless the Physician/CNM's documentation is present. Monitoring: Will monitor 5 charts per week for 4 weeks to ensure that Pitocin is not administered unless all items of the Pre-Oxytocin checklist is complete and documentation of adequate pelvic & cervical exam and estimated fetal weight . Responsibility: Chairman of OBGyn Department	January 3, 2019 January 18, 2019 February 15, 2019

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	Oxytocin sbould not be initiated if the check list is incomplete. b. Review of the clinical record identified Patient #157 was admitted to the hospital for induction of labor on 11/2/18 at 40 weeks and two days gestation. A Pbysician's order dated 11/2/18 at 8:30 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. Review of the clinical record noted that Oxytocin was initiated at 9:19 AM and discontinued at 5:08 PM. A Physician's order dated 11/3/18 at 8:45 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. Review of the clinical record dated 11/3/18 noted that Oxytocin was initiated at 9:56 AM and discontinued at 1:56 PM. Review of the Pre-Oxytocin cbecklist, the clinical record, and interview with the Nurse Manager on 11/19/18 at 2:00 PM failed to provide evidence that the patient's pelvis was documented to be clinically adequate.			
Section 19-13-D3 (c) Medical Records (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).	22. Based on a review of clinical records, interviews and policy review, for one sampled patient reviewed for magnesium sulfate administration, (Patient #159), the facility failed to ensure the patient was monitored in accordance with facility policy. The finding includes the following: Patient #159 was admitted to the Labor & Delivery Unit of the bospital for observation on 6/19/18 at 6:00 PM with complaints of a gusb of fluid at 32 weeks and 6 days gestation. Review of the H&P dated 6/20/18 at 12:22 AM identified that the patient had pregnancy induced hypertension and was noted with elevated blood pressures (BP). The plan of care included administration of steroids, antibiotics, and antihypertensive medication. A physician's note dated 6/23/18 at 12:22 AM identified that the patient's blood pressures were escalating, will proceed with induction of labor due to chronic		Applies to 19-13-D3 (c) Medical Records (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6). Women and Infants nursing staff re-educated to tbe Magnesium Sulfate policy and the necessity for documentation of the patients vitals. This education will be electronic through Healthstream and a required test with a required pass score of 100% . Monitoring: Will audit 5 labor cbarts per week for 4 weeks requiring Mag Sulfate to ensure that all vitals are documented in the chart. Responsibility: Clinical Manager Women and Infants	January 31, 2019 February 28, 2019

hypertension with superimposed severe preeclampsia based on severe-range blood pressures, and administration of IV Magnesium Sulfate for seizure prophylaxis.

a. A physician's order dated 6/22/18 at 11:47 PM directed to administer Magnesium Sulfate 4 gram loading dose IV over 20 minutes. The Medication Administration Record (MAR) dated 6/23/18 noted the medication was administered from 12:30 AM until 12:50 AM. Review of the clinical record and interview with the Manager on 11/20/18 failed to identify that the patient's vital signs were monitored every five (5) minutes in accordance with facility policy. Review of the Magnesium Sulfate policy in Obstetrics directed that during the loading dose, the RN remains at the bedside and assesses BP, respiratory rate, heart rate and oxygen saturation every 5 minutes during the magnesium sulfate infusion.

b. A physician's order dated 6/23/18 at 8:58 AM directed to administer Magnesium Sulfate 2 grams maintenance dose at 75 ccs per hour. The Medication Administration Record (MAR) dated 6/23/18 noted the medication was administered from 12:50 AM through 9:24 AM. Review of the clinical record and interview with the Manager on 11/20/18 failed to identify that vital signs were obtained per policy. Review of the Magnesium Sulfate policy in Obstetrics directed that during the maintenance dose, assess and document: BP, respiratory rate, heart rate and oxygen saturation every 15 minutes for first hour, every 30 minutes for second hour, then hourly.

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Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).	23. *Based on clinical record reviews, review of facility documentation and interviews for one of three sampled patients (Patient #2) reviewed for sequential compression sleeve monitoring, the facility failed to ensure documentation of assessments and/or monitoring of the sequential compression sleeves after placement and/or repositioning of the patient. The findings include: a. Patient #2 was admitted to the same day surgery on 6/11/18 for a scheduled left shoulder arthroscopy surgery and the patient's past medical history included hypertension. Review of the clinical record identified between 9:27 AM to 9:38 AM the patient received a left shoulder Interscalene brachial plexus block administered by anesthesia for pain management. The clinical record identified the Operating Room (OR) table had been adapted with the T-Max shoulder positioner also known as Tenet positioning device for the procedure. The surgical case information notes identified Patient #2 was moved onto the OR table with assist of one and a pillow wedge was used to maintain a sitting position with the knees flexed, all pressure points were padded and the position was checked by MD. The notes further identified the sequential compression device (SCD) was applied to the bilateral lower legs at 45 pressure by RN #108. The intraoperative note identified the patient was in a supine position at 10:57 AM, intubated at 11:12 AM, placed in a beach chair position at 11:20 AM, the surgical incision was made at 11:48 AM and the patient was transferred to the recovery room at 2:24 PM. The nursing flowsheet PACU note on 6/11/18 at 2:26 PM, identified the bilateral pneumatic compression device on, vital signs stable and pain score 0 for pain assessment scale 0-10. The PACU note at 6:30 PM identified Patient #2 was complaining of bilateral lower extremity weakness below the knee and numbness to the feet. The significant event note	Applies to 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1). All nursing staff will be re-educated on the DVT protocol standard of practice to include the documentation of the application or removal of this devices as well as the reassessment of skin integrity, peripheral pulses, proper alignment, edema and changes in sensation and movement every 8 hours. Will create a report from EPIC identifying patients placed in sequential compression devices to assist clinical areas in reviewing real time documentation. Monitoring: Will monitor 5 patients per week for 6 weeks to ensure that documentation of sequential compression devices for reassessment of skin integrity, peripheral pulses, proper alignment, edema and changes in sensation and movement are completed at a minimum of every 8 hours. Responsibility: Director or Professional Practice and Innovation	February 15, 2019 February 15, 2019 March 31, 2019

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	dated 6/11/18 at 8:56 PM by the orthopedic Physician Assistant (PA) identified the patient was complaining of bilateral lower extremity paresthesia, there was no pain and no loss of motor distally, lumbar x-rays were ordered and the patient was admitted overnight for neuropathy. Subsequent nursing flowsheet notes at 10:45 PM identified the bilateral intermittent pneumatic compression device was on, the patient reported numbness, tingling, and decreased sensation, there were weak plantar and dorsi flexions and the MD aware. The neurology consult note dated 6/12/18 at 4:15 PM identified the patient with bilateral foot drop and dysesthesia from the straps on the legs per the patient causing tibial and peroneal neuropathies. The note identified the patient could not walk and the expectation was for the symptoms to improve over the next one to two (1-2) weeks. The note identified the recommendation was to discharge home with physical and occupational therapy, follow up in office in two (2) weeks and order Gabapentin if the symptoms worsen. The discharge summary dated 6/13/18 identified Patient #2 was discharged home with diagnoses of left shoulder rotator cuff repair and acute bilateral tibial and peroneal neuropathies. Review of the clinical record failed to reflect documentation that assessments of the sequential compression sleeves after placement and after repositioning of the patient were completed. In addition, the clinical record failed to reflect that increased frequency of monitoring after the patient complained of bilateral lower extremity weakness along with continued use of the sequential compression device. In an interview on 11/15/18 at 9:10 AM, RN #108 identified the SCD sleeves are placed and turned on while the patient is awake and in the supine position. RN #108 stated for this procedure the head of bed is raised upright and the pillow wedge is placed under the legs after			

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	intubation. RN #108 identified the safety strap is secured across the patient's thighs and readjusted during reposition. RN #108 could not recall if an assessment of the bilateral lower extremities after initial placement of the SCD sleeves was conducted. In an interview on 11/14/18 at 12:15 PM, MD #110 identified the possible causes for Patient #2's bilateral foot drop, and tibial and peroneal neuropathy was compression on the peroneal area (located on the lateral fibula head) and the effect of straps on the lateral part of the leg. In an interview and clinical record review on 11/15/18 at 1:35 PM, the orthopedic Physician Assistant (PA #100) identified she assisted with Patient #2's surgery. PA#100 identified a safety strap was placed mid-thigh while the patient was in supine position, a pillow was placed and pushed up to the buttocks and under the patient's legs for positioning before the patient was repositioned into the beach chair position. PA #100 identified Patient #2 was of moderate size and sometimes the size of the patient's legs will cause external rotation. In an interview and record review on 11/19/18 at 11:40 AM, RN #111 identified she cannot recall details of the patient's complaining of leg discomfort but the standard practice is to check and document the placement of the compression sleeves before turning the SCD on. Review of the facility's sequential compression therapy standard of practice identified the sleeve should fit snugly but not tightly, check the fit by inserting two fingers between the sleeve and the patient's leg at the knee opening and to document application. In addition to assess the patient's skin under the sleeves at least every eight (8) hours to avoid skin breakdown, assess the extremities for peripheral pulses, edema, changes in sensation and movement at least once each shift. Review of the facility's patient positioning policy identified during and immediately after positioning to assess and		

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	maintain proper body alignment and tissue integrity. Reassessments are made following repositioning or any movement of the patient, bed or positioning devices.		
Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Staff (1).	24. Based on review of the medical record and interviews for 1 (P#128) of 9 patients reviewed for pain management the hospital failed to ensure pain assessments were completed according to facility policy. The findings include: a. Patient (P) #128 was evaluated in the Emergency Department (ED) on 11/8/18 for chief complaints of chest pain and chronic back pain. During a review of the medical record with the ED Nurse Navigator, ED Manager and Registered Nurse (RN) #106 it was identified P#128 arrived in the ED at 2:35 AM. An initial triage nursing assessment completed at 2:50 AM and additional assessments between 2:52AM and 6:30 AM failed to identify P#128's pain assessment was completed. In addition according to the medical record P#128 received Ibuprofen and Tylenol for pain however the medical record failed to identify a pre and post pain score had been completed with the administration of the pain medications. Hospital Pain Management policy indicated an initial assessment of pain was to be completed rating the severity numeric on a scale of zero to ten. In addition routine reassessment of pain is completed according to the routine schedule for vital signs. Lippincott Procedures for Pain Management dated November 17, 2017 indicated the pain relief intervention used should be documented in addition to the patients rating of pain before and after pain management interventions.	Applies to 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Staff (1). Emergency Department Nursing re-educated to hospital's Pain Management policy and the necessity to score the patient's pain level prior to and after pain medication administration. Monitoring: Will monitor 10 charts per week for 6 weeks to ensure that the appropriate recording of pain levels are documented prior to pain medicine administration and that a reassessment occurs within the appropriate time after administration . Responsibility: Clinical Manger Emergency Services	February 15, 2019 March 31, 2019

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Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).	25. Based on clinical record review and staff interview for 1 of 3 sampled residents reviewed for medical record accuracy, (Patient # 15) the facility failed to accurately reflect a patients diagnoses. The findings include: a. Patient # 15 was admitted to the hospitsl on 12/24/17. Review of the History and Physical dated 12/24/17 identified the patient had a diagnoses of type 2 Diabetes Mellitus. Review of the hospital discharge summary dated 1/5/18 identified Diabetes Mellitus type 2 as a discharge diagnosis. Interview with MD #114 on 11/19/18 2PM stated that the patient was not a diabetic and did not know how it got into the chart. MD # 114 stated that he would make a note in the chart to correct that.	Applies to 19-13-D3 (c), 3 (e), 2 (i), (d); Credentialed Medical Staff were re-educated to the hospital policy for Use of Copy/Paste or Similar Functionality in the Electronic Health Record and the risk associated with using this function. The Medical Staff was made aware that they are responsible for confirming the accuracy of their clinical documentation. Monitoring: Will audit 5 charts per week for 4 weeks to ensure that the cut and paste function within the electronic health record is used appropriately. Responsibility: Director of Regulatory and Medical Staff Affairs	January 5, 2019 January 31, 2019
Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).	26. Based on clinical record review, interview and policy review for one patient (Patient #107) the facility failed to ensure that a physician assessment was documented and failed to ensure that nurse documentation of patient blood pressures were documented accurately. The findings include the following: a. Patient #107 was admitted on 4/11/17 for a laparoscopic cholecystectomy. A nursing pre-operative assessment identified a blood pressure of 129/76. A preoperative anesthesia assessment identified the patient's blood pressure as 129/72 at 7:15 AM. The patient arrived in PACU at 8:36 AM with a pain scale of 0/10 (10 worst) and a pain of 10/10 at 8:56 AM. Patient #107 received IV anxiolytic and pain medications. Pain at 9:35 was 4/10 and at 10:42 AM was 10/10. Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was completed at 10:35 AM for post-operative analgesia. The anesthesia record identified the patient's blood pressure was 93/59, heart rate was 68, the patient was sedated, following commands, stable and tolerated the procedure well. Pain score was 3/10	Applies to 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1). A new policy was put into place which addressed the requirement that a progress note is to be written immediately by the physician/provider in the patient's medical record for any patient experiencing a significant change in their clinical condition. The policy lists 9 examples of conditions that would require an immediate progress note. Currently, the Bylaws had addressed that a progress note was to be written "daily". Change in Patient's Condition policy was communicated to the Medical and Surgical Residents and all members of the credentialed medical staff. All new providers applying for privileges at Saint Mary's Hospital will also attest to their acknowledgement of the policy. Monitoring: Will audit 5 patient records a week for 4 weeks to ensure that all physician notes are present and timely, specifically for patients with a significant change in their clinical condition.	January 3, 2019 January 5, 2019 January 31, 2019

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	post procedure at 10:46 AM. Nursing notes dated 4/11/17 at 10:56 AM identified that Patient #107 was fully awake, out of bed to the bathroom, felt dizzy and faint, and had a blood pressure of 77/44. The physician was notified and 1 liter of lactated ringers was administered. A blood pressure recheck was 96/53. Patient stated he/she felt better with no further dizziness or feeling faint. Review of nursing post-operative vital signs indicated that the patient's BP remained at "+/- 20 pre-op" or within 20mm Hg of pre-anesthetic systolic level for a high of 149 to a low of 109 at 10:00 and 10:56 despite documented blood pressures of 93/59 and 96/53 respectively. According to a nurses note dated 4/11/17 at 10:48 AM a physician was in to assess the patient. However, the clinical record failed to reflect a documented assessment by the physician. Patient #107 was discharged per post-anesthesia protocol at 2:00 PM with discharge instructions. Interview with the Quality Specialist on 11/16/18 at 10:00 AM indicated that when the case was reviewed it was determined that the surgical resident was notified of the patients dropping blood pressure, saw the patient, ordered IV fluids and asked to be called after the fluids were administered however failed to write a note. Review of the medical staff bylaws indicated that progress notes content shall be sufficient information to permit continuity of care.	Non-compliance will be addressed by the Department Chairman. <u>Responsibility:</u> Director of Regulatory and Medical Staff Affairs	

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Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).	27. Based on a review of clinical records, interviews and policy review, for one sampled patient reviewed for magnesium sulfate administration, (Patient #159), the facility failed to ensure the record accurately reflected the time frame in which the medication was administered. The finding includes the following: a. Patient #159 was admitted to the Labor & Delivery Unit of the hospital for observation on 6/19/18 at 6:00 PM with complaints of a gush of fluid at 32 weeks and 6 days gestation. Review of the H&P dated 6/20/18 at 12:22 AM identified that the patient had pregnancy induced hypertension and was noted with elevated blood pressures (BP). The plan of care included administration of steroids, antibiotics, and antihypertensive medication. A physician's note dated 6/23/18 at 12:22 AM identified that the patient's blood pressures were escalating, will proceed with induction of labor due to chronic hypertension with superimposed severe preeclampsia based on severe-range blood pressures, and administration of IV Magnesium Sulfate for seizure prophylaxis. A physician's order dated 6/23/18 at 9:00 AM directed to administer Magnesium Sulfate 1 gram bolus over 60 minutes. Review of the MAR noted that the medication was administered during the period of 9:23 AM through 10:23 AM. Review of the flow sheets dated 6/23/18 at 9:24 AM identified that Magnesium Sulfate 3 g/hr. was administered at 75 ml/hr., a discrepancy compared to the MAR. Interview with the Manager on 11/20/18 at 3 PM stated this was an error in documentation and should reflect that the Magnesium Sulfate 1 gram bolus was being administered on 6/23/18 from 9:23 AM through 10:23 AM.	Applies to 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1). Women and Infants nursing staff re-educated to the Magnesium Sulfate policy and the necessity for documentation of the patients vitals. This education will be electronic through Healthstream and a required test with a required pass score of 100% . Monitoring: Will audit 5 labor charts per week for 4 weeks requiring Mag Sulfate to ensure that all vitals are documented in the chart. Responsibility: Clinical Manager Women and Infants	January 31, 2019 February 28, 2019

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Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (g) Pharmacy and/or (i) General (6).	28. *Based on clinical record review, interview and policy review for one patient (Patient #6) the facility failed to ensure that medications were available for administration in a timely manner. The findings include the following: a. Patient #106 presented to the ED on 1/23/18 at 5:00 PM with a past medical history of hyperthyroidism presented from a PCP office with complaints of shortness of breath, palpitations, nausea and vomiting. The patient had a productive cough with brown and blood tinged sputum. The note indicated that the patient had a history of hyperthyroidism and had been non-compliant with Methimazole (thyroid medication) for greater than one month. The patient was noted to have a new onset of atrial fibrillation in the setting of hyperthyroidism and poor medication compliance. The ED note indicated that the patients Thyroid Stimulating Hormone (TSH) level was 0.0. Pysician orders dated 1/23/18 at 11:42 PM directed to administer Methimazole 20 mg. A physician note dated 1/24/18 at 4:54 AM indicated Methimazole was unavailable and PTU 300 mg was ordered on 1/24/18 at 4:43 AM. The MAR indicated that the medication was administered at 1/24/18 at 4:58 AM. Review of the physician's note dated 1/24/18 at 4:54 AM indicated pharmacy contacted and Methimazole and PTU were not available. Several resources were activated to reveal a single dose of PTU was available in the ED and was administered to the patient. Interview with RN # 110 on 11/19/18 at 11:30 AM indicated that when she assumed care of Patient #106 on 1/23/18 into 1/24/18, the Methimazole had been ordered (at 11:53 PM) but not yet given. RN #110 indicated that she was trying to get the medication and had called the pharmacist on-call because the pharmacy is closed at 12:00 AM. According to RN #110, the on-call pharmacist indicated that the	Applies to 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (g) Pharmacy and/or (i) General (6). PTU was available in the ED at the time of this event. PTU was made available additionally in the ICU. PTU and Methimazole have been permanently made available in both Emergency Department and Intensive Care Unit accudoses. Nursing staff no longer need to go through Pharmacy for these medications. Thyroid Storm education provided at Medical Grand Rounds to Residents & Nursing. Monitoring: Inventory levels are continuously monitored in Accudose. When it falls below a par level the medication is replaced by pharmacy personnel. Responsibility: Director of Pharmacy	February 1, 2018 April 3, 2018 & December 11, 2018 Indefinite

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	medication was not available. RN # 110 indicated that she called the physician (approximately 4:43 AM) and notified her that the medication was unavailable and is was then that the physician ordered the PTU medication. Interview with the Nurse Supervisor #100 indicated that she was not aware that the medication was unavailable. The Supervisor indicated that if she had been made aware, there is an online listing of all medications in house and where they are located. Nurse Supervisor #100 indicated that if a medication is unavailable a Pharmacist can be called in. Review of the record with the Quality Coordinator failed to reflect a nurse's note related to the unavailability of the medication and/or the steps taken to obtain the medication between 1/23/18 at 11:42 and 1/24/18 at 4:43 AM. Interview with the Assistant Pharmacy Director on 11/15/18 at 1:09 PM identified that telepharmacy services are available 24/7. On 1/24/18, Methimazole was available in the pharmacy and PTU was available in the emergency department. Since this incident, the hospital has increaced the availability of these medications.		

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Section 19-13-D3 (f) Diagnostic and therapeutic facilities and/or (i) General (6).	29. Based on document review, observations and/or interviews, the hospital failed to ensure that safety precautions were maintained and/or monitored for radiological services. The findings include: a. The scope of the DEEP inspection was review St. Mary's Hospital's compliance with DEEP's Administrative Regulations Section 19-24-1 through 19-24-14 and the Regulations pertaining to the Center for Medicare/Medicaid Services (CMS). The inspection consisted of observations, interview of hospital staff, an interview of the Chairman of the Radiation Safety Committee and a review of documents pertinent to the radiation protection program of St. Mary's Hospital. Within the inspection the following violation was noted: Section 19-24-8 of the DEEP's Administrative Regulations "Radiation Information Labeling" states: Each area or room in which sources of ionizing radiation other than radioactive materials are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and appropriate wording to designate the nature of the source or sources of ionizing radiation (example below) CAUTION * X-RAY Additionally, section 19-24-8 also states: CAUTION * RADIATION AREA This provision shall not apply to areas or rooms where x-ray equipment is used solely for diagnostic purposes by or under the direction of a healing arts practitioner as authorized by law" Contrary to this, your CAT scan rooms which utilize X-Ray devices were posted "Caution Radiation Area" and one of the entrances to X-Ray room number one was not posted at all.		Applies to 19-13-D3 (f) Diagnostic and therapeutic facilities and/or (i) General (6). Radiation signs changed from Caution Radiation to Caution Xray were corrected on site. In addition, the annual physicist report will be re-formatted to flow with the required elements stated in Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21. The specific format that will be followed is from NUREG 1556, volume 9, appendix L. This format will be adapted with the previously reported 2017 patient safety and ALARA data. The upcoming 2018 report data will follow the same format. Monitoring: Will audit caution xray signs monthly for one year to ensure that they are not replaced or removed. Responsibility: Director of Imaging Services	October 17, 2018 January 31, 2019

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	It was noted this was corrected and all rooms inspected were properly posted by the completion of the inspection. Additionally, Section 482.26 (b): "Standard Safety for Patients and Personnel" of the CMS Regulations states-"The radiologic services, particularly ionizing radiology procedures must he free from hazards for patients and personal". It continues with "Consistent with the requirements under the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21, the hospital must monitor the quality and safety of radiological services." Contrary to this, St. Mary's failed to comply with this standard in reference to performance of an annual radiation protection program audit.			
Section 19-13-D3 (h) Dietary Service.	30. Based on observations, review of facility documentation and interviews, the facility failed to ensure opened food items were stored according to standards of practice. The findings include: a. During tour of the kitchen with the Food Service Director on 11/19/18 it was identified on a wired shelve rack that multiple opened items were stored inappropriately, the following observations were made: -an open packet of yellow cornmeal, the top was twisted and secured with plastic wrap fashioned into a tie closure, the manufacturer's expiration date was 12/15/18, there was no date to identify when the packet was opened. -an open packet of cream based soup mix, dated 12/20, there was no manufacturer's expiration date, the top was loosely twisted with the contents exposed and plastic wrap was loosely fashioned into a tie closure. -an open packet Italian Farro grain with no date to identify when the packet was opened, the manufacturer's expiration date was 1/18/19, the top of the packet was loosely twisted with the contents		Applies to 19-13-D3 (h) Dietary Service: All dietary staff re-educated to the Food Product Shelf Life and Food Safety Product Labeling & Dating Guidelines. Staff re-educated that all product must have an expiration date as well as the open date identified on the opened product and that the product must be completely sealed. Monitoring: Monitoring for open product and dating has been incorporated in to the management daily rounding. Will monitor daily to ensure that the open and expiration date is on the food products and that the product is stored and covered properly. Responsibility: Director of Food and Nutrition	November 27, 2018 Indefinite

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	exposed, and plastic wrap was loosely fashioned into a tie closure. -an open packet of batter tempura mix, the top was rolled and folded, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date. -an open packet of Thai chili sauce mix, the top was rolled and folded, there was no date to identify when the packet was opened, there was no manufacturer's expiration date, and the packet had food stains. -an open packet of whole wheat flour with the top rolled and folded, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date. -an open packet of powdered instant non-fat dry milk, the top was loosely twisted, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date. Upon surveyor inquiry the identified items were removed and discarded. In an interview on 11/19/18, the Director of Food Services identified it was expected that all food items are dated when opened and that the manufacturer expiration date which is either found on the item or on the box the items were delivered in is followed. The Director of Food Services stated if there was a question regarding the expiration date, it is expected that staff follow the shelf life guidelines. Review of the Food Product Shelf Guidelines identified in part, that opened non-fat dry milk should be stored in an airtight container for three (3) months, cornmeal should be kept tightly closed in dry storage for eighteen (18) months, whole wheat flour kept in dry storage for six (6) months and sauce mixes kept in storage for six (6) to twelve (12) months.		

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Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.	31. Based on clinical record review, interview and policy review the facility failed to ensure that infection control techniques were utilized. The findings include the following: Tour and observation in the Cardiac Catherization lab was completed on 11/13/18 during the period of 9:30 AM through 10:00 AM. a. Observation of staff in Room 2 identified two staff members whose hair covering failed to encompass all of their hair. Review of the policy indicated surgical head covers or hood thatcover all scalp skin and hair will be worn. b. Observation 11/13/18 at 9:45 AM identified RN #102 with gloves on prepping the patients left groin area. The RN removed her gloves and went to the supply cart and obtained new gloves failing to perform hand hygiene after glove removal. RN #102 donned clean gloves returned to the table, removed a drape, discarded the drape, remove gloves and proceed to the computer then to the medication delivery system failing to perform hand hygiene. c. RN #103 was observed on 11/13/18 at 9:55 AM in the cath lab without gloves on pick up a wrapper off the floor and discard it, and failed to perform hand hygiene after. Review of the facility policy indicated perioperative staff will perform hand hygiene before entering the invasive procedure room. The policy indicated all personnel moving within or around a sterile field will do so in a manner that prevents contamination of the sterile field.	Applies to 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control a & b: A new policy was established specifically for the cardiac cath lab. All Cardiac Cath Lab staff, Cardiologists, ED Physicians will be educated on the new Cardiac Cath Lab Infection Control Attire policy which specifies that head and facial hair are covered in restrictive areas. A mask will be in place once surgical supplies are opened and gloves will be worn depending on the task. A personal protective equipment (PPE) locker will be installed immediately outside cath lab for easy access of PPE for cath lab staff, Physicians, ED staff or paramedics entering the unit. Monitoring: Will audit compliance with appropriate donning of PPE, including head covers, gloves and face mask daily for 4 weeks. Responsibility: Manager of Cardiac Cath Lab Applies to (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control c: All cath lab staff re-educated to the hospital's Cardiac Cath Lab Infection Prevention Attire policy. Education included in person education by the Infection Prevention Department with cath lab staff expected to return demonstration of appropriate hand hygiene and glove use. Monitoring: Will audit compliance with Daily observation checklist for 4 weeks for appropriate hand hygiene and gloving. Responsibility: Manager of Cardiac Cath lab	January 31, 2019 January 31, 2019 February 28, 2019 January 31, 2019 February 28, 2019

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Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.	32. Based on observations and interviews, the facility failed to ensure an Intravenous (IV) irrigation bag was stored according to the standards of practice. The findings include: a. During tour of the Operating Room (OR) department on 11/8/18, it was identified in OR Room #4 (the urology procedure room) that a three (3) liter irrigation bag of normal saline was hanging in a pressurized device without the benefit of an outer cover. Upon surveyor inquiry, it was identified that the OR room was not used earlier nor was there a procedure scheduled for that day 11/8/18. In an interview with the Infection Control Nurse (ICN) it was identified that the outer cover of an IV bag should remain in place until ready for use.	Applies to 9-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control. OR Circulating Nurse is responsible to ensure that all IV bags are removed from an operating room after the patient leaves the room. This responsibility is documented in the Circulating Role in the OR policy as well as their job description. The OR Circulating nurses re-educated to this responsibility. Monitoring: Will monitor daily for 4 weeks to ensure that the OR rooms are cleared of all discarded medications and IV bags. Responsibility: Director of Surgical Services	November 17, 2018 December 31, 2018
Section 19-13-D3 (c) Medical Staff (2)(B) and/or (i) General (6).	33. *Based on observations, facility documentation and interviews for one of three glucometers, the facility failed to ensure the glucometer was disinfected according to manufacturer's recommendation and/or that infection control recommendation was implemented. The findings a. During tour of the Operating Room (OR) department and surveyor inquiry on 11/8/18, it was identified that the glucometer in the main OR was not disinfected according to the manufacturer's directions. In an interview on 11/8/18, ORA #1 identified he/she cleans the glucose meter with alcohol wipes. In an interview on 11/8/18, the Infection Control Nurse identified bleach wipes are available and should be used to disinfect the glucose meter. Review of the Glucose Meter basic operating and maintenance information policy identified in part, to clean the outside of the meter with an approved disinfectant cloth after each patient use.	Applies to 19-13-D3 (c) Medical Staff (2)(B) and/or (i) General (6). All OR staff re-educated on the appropriate product for cleaning glucometers. Current policy dictates that glucometers are wiped with Chlorox Germicidal wipes. All OR glucometer caddy cases are posted with a sign stating that chlorox germicidal wipes are to be used. Monitoring: Will audit 5 times per week for 4 weeks that staff can verbalize the appropriate way to clean glucometers in the OR. Responsibility: Director of Surgical Services	November 17, 2018 November 18, 2018 December 31, 2018

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Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).	34. *Based on a review of clinical records, facility documentation, interviews, and policy review, for one of three patients reviewed for vena cava filter removal (Patient #124), the hospital failed to ensure that the catheter was removed in its entirety. The finding includes: a. Review of Patient #124's clinical record identified that the patient signed informed consent on 5/19/17 at 2:40 PM for the removal of the inferior vena cava (IVC) filter with associated risks that included bleeding and/or infection. Review of the operative report authored by MD #116, dated 6/13/17, identified that the patient had the IVC filter removed under ultrasound-guidance. The needle, instrument, and sponge counts were correct at the end of the case and the patient tolerated the procedure well. The total fluoro time was not documented in the operative record. Although the post-operative note reflected that MD #114 (Interventional Radiologist) was consulted intraoperatively for assistance, the operative note failed to note why the IR physician was consulted. Review of MD #114's note dated 6/13/17 identified that MD #116 requested assistance during the procedure. Using fluoroscopic assistance, a 4 French glide catheter was used through the indwelling right internal jugular access sheath to advance the glide wire from the superior vena cava (SVC) to the IVC (inferior vena cava), after which the glide catheter was advanced over the wire into the IVC and from this point MD #116 completed the procedure and MD #114 left the operating room. On 6/13/17 at 11:29 AM, MD #117 (Resident) directed th epatient to have a chest x-ray to rule out pneumothorax with a subsequent order at 12:20 PM, may discharge home, x-ray read by MD #117 (Resident). Review of the chest x-ray result dated 6/13/17 at 11:43 AM identified coiled radiopaque density right	Applies to 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6). All IVC filters are now removed by an Interventional Radiologist in the Interventional Radiology procedure room under guided fluoroscopy due to their expertise and their high volume of insertion and removal of these devices. Monitoring: The OR schedule was monitored weekly for 6 weeks to ensure that no cases of IVC filter removals were scheduled. Responsibility: Chairman of Department of Surgery	June 26, 2017 August 15, 2017

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	infrahilar region, which may represent a retained foreign body, less likely an overlying structure although may be confirmed with PA and lateral views. No appreciable consolidation or pneumothorax. Results called to MD #116. This report was authenticated by a radiologist on 6/13/17 at 1:00 PM. Review of a chest CT dated 6/13/17 at 4:51 PM noted opaque foreign body, likely retained products from the IVC filter removal, within the right lower lobe vessels, likely within the pulmonary artery. Review of the interventional radiology (IR) procedure note dated 6/15/17 at 5:35 PM identified that MD #115 noted that the patient had the IVC filter removed intraoperatively on 6/13/17 with subsequent imaging that demonstrated a large foreign body in the right pulmonary artery. The foreign body retrieved appeared to be a 37 centimeter (cm) long stretched catheter fragment that was sent to pathology. Review of the pathology report dated 6/16/17 identified that the foreign body was that of soft pliable catheter measuring 37 cm and appears to show partial diameter segment of the catheter of unknown original diameter. Record review and interview with MD #116 on 11/20/18 at 11:30 AM stated the filter was noted to be tipped on the venogram and he was having difficulty therefore requested the assistance of an interventional radiology physician. MD #116 stated MD #114 went inside his snare, already in place, with a smaller one then MD #116 was able to retrieve the filter. MD #116 stated that although he inspected the catheter after the procedure, it was "hair like to the naked eye and appeared ok" and was unsure if the retained catheter was the one he used or the one MD #114 used during the procedure. Record review and interview with MD #115 on 11/20/18 at 1:30 PM stated although he was not		

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	present during the retrieval of the filter on 6/13/17, it was his opinion that the snare utilized during the procedure may have been too large and sheared the catheter. Record review and interview with the Quality Manager on 11/20/18 at 3PM stated that MD #117 noted that the patient did not have a pneumothorax and subsequently discharged the patient on 6/13/17, however, failed to identify the retained foreign body. The Manager stated that it was the Radiologist who noted the retained foreign body after the patient left the hospital and was called back for an additional x-ray and chest CT to confirm the retained foreign body. Review of the corrective action plan (CAP) with the Quality Manager stated the hospital was unable to determine when and/or why the piece of the glide catheter fractured because the main piece of the glide catheter was disposed of prior to the investigation. Subsequent to this incident, all IVF filter removals will take place in the interventional radiology department by an interventional radiologist. The CAP was verified as implemented during the onsite visits. Review of the Prevention of Retained Surgical Items policy directed staff to take measures to prevent intravascular device (catheter, guidewire, sheath) fragments by the following, in part, insert and remove intravascular devices in accordance with the manufacturer's IFU, inspect devices before use to identify defects, do not withdraw catheters and guidewires through a needle (if the catheter or guidewire is replaced, withdraw it simultaneously with the needle), account for the device in their entirety by inspecting for breakage immediately on removal from the patient.		

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Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).	35. *Based on clinical record review and policy review the facility failed to ensure that for 1 of 2 patients (Patient #130) on a ventilator that the clinical record reflected the rationale for a change in the ventilator settings. The findings include the following: a. Patient #130 was admitted on 11/7/18 with shortness of breath, pneumonia, acute respiratory distress syndrome, and congestive heart failure. The record indicated that on 11/8/18 at 3:00 AM the patient was intubated. Review of the physician's orders dated 11/8/18 order at 5:01 AM directed an assist control, FiO2 of 80, PEEP of 10 and titrate FiO2 to keep saturations above 92%. The order dated 11/8/18 at 5:39 AM directed a FiO2 of 80 and titrate FiO2 to keep saturations above 92%. Review of the RT documentation indicated that on 11/8/18 at 5:30 the patient vent was set with a PEEP of 8 and FiO2 of 70 %, the failed to reflect that the vent was set based on the physician orders. Review of the Oxygen Saturations with RT #100 indicated that on 11/8/18 at 5:00 AM the patient's oxygen saturation was 97%, 92% at 5:30 AM and at 6:00 AM. The record failed to reflect the rationale for the titration of the FiO2 to 70% in relation to failing to meet physician direction to maintain a saturation of greater than 92%. Interview with RT #100 on 11/8/18 at 10:40 AM indicated that there should be a RT note for the rationale for the titration of the FiO2. RT #100 indicated that she increased the patients FiO2 at the beginning of her shift secondary to the patient "breathing too fast" and a saturation of 91%.	Applies to 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6). Medical and Surgical Residents have been instructed that they are not authorized to change vent settings. They may place orders only. ICU attending's and Pulmonologist have been educated that before adjusting vent settings that an order must be immediately entered into the electronic health record. Respiratory Therapy staff have been educated that no changes to the vent settings without an order. Monitoring: Will monitor 5 records per week for 4 weeks that ventilator orders match ventilator settings. Responsibility: Director of Respiratory Services	January 5, 2019 January 12, 2019 December 21, 2019
Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (f)	36. *Based on clinical record review, interview and policy review the facility failed to ensure that for one of three patients (Patient #23) having a bronchoscopy that medications were administered based on a physician's order and/or per manufacturer's recommendations. The findings include the following:	Applies to 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6). Hurricane spray and Cetacaine Spray removed from hospital formulary due to the increased risk of Methemoglobinemia when compared to Lidocaine. In	September 30, 2017

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Diagnostic and therapeutic facilities and/or (i) General (6).	a. Patient #123 presented to the ED 0n 5/19/17 with general weakness. Review of the critical care H&P dated 6/1/17 at 1:22 PM indicated that the patient had a history of breast cancer, chronic obstructive lung disease. The patient had a bronchoscopy on 6/1/18, review of the record indicated that at 9:35 AM, 2% Lidocaine was not available and 20% benzocaine 1 second spray was administered times three. The record failed to reflect the presence of an order for the 20% benzocaine and/or the 2% Lidocaine. Interview with RT #101 on 11/15/18 at 10:00 AM indicated that she was not aware of the correct dose and administered two sprays and then checked for a gag reflex and since the patient had a gag reflex administered one more spray. b. Review of the physician's procedural note dated 6/1/17 indicated that 2% Lidocaine topical solution 3 cc's was administered before the procedure. The record failed to reflect that the respiratory therapist notified the physician of the medication not being available. Interview with the Quality Manager on 11/15/18 at 9:00 AM indicated there was no policy and/or protocol to support the practice of RT administered the medication absent a physcians order. c. In addition review of the manufacturer's direction for use indicated that ½ second of spray should be administered with the ability to repeat times one. The MDU directed that the recommended dose not be exceeded. The note indicated that at 11:05 AM the procedure was completed, the patient had a saturation of 91% on a 50% venti mask. At 11:40 AM the patient desaturated to 69-70 % paced on 15 liters, 100 mg of methylene blue was administered.	addition, dosing accuracy with the spray mechanism on the benzocaine spray is inferior to the use of Lidocaine with atomizer. Lidocaine 4% along with Methylene Blue were stocked in all relevant clinical areas. Standardizing the use of a single-use atomizer throughout the organization (excluding anesthesia) instead of an atomizer that would require sterilization between each use. Education was completed and that the Hurricane and Cetacaine spray will no longer be on the hospital formulary, and educate on the substitution of Lidocaine in its place. The education will also include Methemoglobinemia and the proper indication and administration of Methylene Blue. Revision of Bronchoscopy Assist policy which specifies type of medication to be used and that it should be given via nebulizer. Respiratory Therapy staff educated to revised policy. Monitoring: Monitored pharmacy formulary monthly to ensure that Cetacaine Spray and Benzocaine spray remained unavailable to any staff for one year. Respiratory staff performing bronchoscopy procedures were audited by the Chairman of Pulmonary Services to ensure that perioperative medication orders matched what was administered. Responsible Person: Clinical Manager of Respiratory Therapy	August 2, 2017 September 30, 2018 August 31, 2018